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HEALTH AND SENIOR SERVICES
OFFICE OF MANAGED CARE
ORGANIZED DELIVERY SYSTEMS

Proposed New Rules: N.J.A.C. 8:38B

Authorized By: Clifton R. Lacy, M.D., Commissioner, New Jersey State Department of Health and Senior Services.

Authority: N.J.S.A. 17:48H-32.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2003-52.

Submit written comments by April 4, 2003 to:

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The agency proposal follows:

Summary

These proposed new rules are being promulgated in accordance with P.L. 1999, c.409 (codified as N.J.S.A. 17:48H-1 et seq.), hereinafter referred to as "the Act." The Act was enacted on January 18, 2000, and became effective on June 16, 2000. The Act creates a new entity referred to as an "organized delivery system," or "ODS." An ODS is an entity that, among other things, has the capacity to contract with insurers, health maintenance organizations and medical, hospital and health service corporations (collectively, "carriers"), to provide or arrange for the provision of health care services to individuals covered under one or more of a carrier's health benefits plans delivered in New Jersey.

The Act essentially requires that an ODS either becomes certified by the Department of Health and Senior Services (Department) or licensed by the Department of Banking and Insurance (DOBI). Whether the ODS must become certified or licensed depends upon whether the ODS is accepting financial risk from the carrier. ODSs that do not accept financial risk must become certified by the Department; ODSs that accept financial risk must become licensed by DOBI. Some examples are set forth in Exhibit 8 of the proposed Appendix. In addition to meeting financial standards established by DOBI, however, ODSs that become licensed must meet non-financial standards established by the Department. Rules regarding licensing are being promulgated separately by DOBI. These proposed rules establish standards and procedures applicable to certification, and the recommendation-for-licensing review to be performed at the Department.

These proposed rules interpret the definitions established by the Act; establish procedures and standards for submission by ODSs of applications for certification; establish the procedures and standards by which the Department will review an application for certification; establish procedures and standards for modification, renewal and revocation of a certification; establish standards for winding-up of an ODS' business in the event of revocation; and establish fees relevant to certification applications, modifications and renewals. These proposed new rules also establish the standards that an ODS applying for a license must meet in order for the Department to make a positive recommendation to DOBI with respect to the licensing application.

The Department has made a number of interpretations of the Act in an effort to clarify those entities that the Department believes should be filing for certification. In accordance to the proposed new rules, an ODS is an entity with defined governance that has the capacity to contract with carriers for the provision of health care services to the carrier's covered persons. Excluded from this definition, however, are licensed health care facilities (including laboratories) and health care professionals.

Pursuant to the proposed new rules, not all ODSs are required to file for certification simply because they are not required to be licensed in accordance with the statutes or rules promulgated by DOBI. These proposed new rules specify that an ODS is only required to be certified if it contracts directly with a carrier. Thus, where there may be multiple ODSs involved in an arrangement, only the ODS that contracts directly with the carrier is required to be certified. For instance, if a preferred provider organization, or PPO, contracts with individual practice associations, or IPAs, in order to form a network, and then leases the network to a carrier, the PPO must be certified, but the IPAs do not have to be certified on the basis of that particular contract. If one of the IPAs contracts directly with another carrier, however, the IPA may be required to be certified because of this other contracting arrangement.

Even if an ODS contracts directly with a carrier, there may be some situations in which the ODS will not be required to be certified. The following entities that meet the definition of an ODS are not required to file for certification, even though they may contract with a carrier: an entity licensed as a carrier; an entity regulated by N.J.S.A. 18A:64G-1 et seq. (which established the University of Medicine and Dentistry of New Jersey); an entity that solely provides pharmaceutical services; an entity that solely provides case management services (as that term is defined by the proposed rules); and an entity that solely provides employee assistance plans. Also, an entity composed of health care professionals that contracts directly with a carrier solely for the performance of health care services by the health care professionals, within their respective scopes of license, need not be certified in order to contract with the carrier, if all of the health care professionals are shareholders or employees of that entity (for instance, a professional corporation or professional association formed in accordance with the Professional Service Corporations Act, N.J.S.A. 14A:17-1 et seq.).

The standards on which the Department will base its review of an ODS application, whether for certification or licensing, are substantially similar, and are related to the function that the ODS states it will perform under its contract with the carrier(s). Carriers, in order to administer health benefits plans, whether managed care plans or not, engage in a number of activities that can be, and have been, contracted out to other entities, some of whom meet the definition of an ODS, some of whom do not. For example, carriers may have to engage in, or contract for, network recruitment and retention, credentialing and recredentialing of participating providers, utilization management, complaints handling and investigation, appeals handling and

review, formation and maintenance of protocol and practice committees, claims administration, and marketing, among other activities. If an ODS specifies that it performs, or wants to perform, an activity on behalf of a carrier in addition to the delivery of health care services, the Department will hold the ODS to substantially the same standards that apply to the carriers on whose behalf the ODS intends to perform. An ODS that contracts with multiple types of providers will have to meet the most stringent standards applicable to the business of the carriers with which it contracts.

The Department believes that using a functional approach is reasonable given the diverse nature of the ODSs and the diverse nature of the activities in which ODSs may engage on behalf of a carrier. Some ODSs are quite large, and have both the capacity and the willingness to perform most of the activities that a carrier may be required to perform with respect to the carrier's health benefits plans that are managed care plans. Other ODSs are interested in being more specialized, and taking on only some portion of a carrier's activities (for instance, providing a network of health care providers for mental health services, establishing and administering utilization management guidelines and clinical criteria for the mental health services, addressing complaints, and handling the first stage of appeals related to the provision of mental health services, and managing the fees and fee pools allocated to the health care providers in its network). Still others are interested in offering the health care services that those providers who are affiliated with the ODS are licensed to provide, and collecting data therefrom, but may choose to limit their other activities to the provision of support services to affiliated health care providers. Not all ODSs are especially interested in taking on administrative duties of the carrier. Nor, for that matter, are all carriers willing to have all ODSs take on certain activities.

The Act, at N.J.S.A. 17:48H-33, states that licensed and certified ODSs are subject to the Health Care Quality Act, P.L. 1997, c.192 (as codified, generally: N.J.S.A. 26:2S-1 et seq.). The Department believes that the most reasonable way to apply the provisions of the Health Care Quality Act, and rules promulgated pursuant thereto, given the diverse nature of ODSs, is to base applicability of those laws on the functions that the ODS performs on behalf of one or more carriers. Hence the functional approach emphasized by the proposed new rules. Proposed N.J.A.C. 8:38B-1 sets forth the most general provisions of the new chapter. This proposed new subchapter establishes the scope of the chapter and definitions that apply throughout. This proposed new subchapter also establishes the compliance time frames applicable for the chapter. The proposed new subchapter addresses the matter of suspension or revocation of a certification, and recommendations to suspend or revoke a license, and addresses other penalties for noncompliance (as set forth by the Act). The proposed new subchapter establishes confidentiality standards, both with respect to the standards ODSs are expected to meet regarding member information, and those documents submitted to the Department that will be maintained as confidential or proprietary.

Proposed N.J.A.C. 8:38B-2 establishes the procedures and basic standards for submitting a complete application for certification, as well as the basic standards for completing an application for licensing specific to the Department's review provided in consultation to DOBI. The proposed new subchapter also establishes procedures and standards for submitting a complete application for modification of a certification, including when a modification of the certification is required. The proposed new subchapter also establishes procedures and standards for submitting a complete application to renew a certification.

Proposed N.J.A.C. 8:38B-3 sets forth the standards applicable to each of the functions for which an ODS may be certified in addition to the performance of health care services. These functions include: network recruiting and retention; credentialing and recredentialing; utilization management development; utilization management application; quality assurance and continuous quality improvement; complaint administration; utilization management appeal administration; and, claims administration. It may be noted that the functions, and standards therefor, are not necessarily mutually exclusive categories. For example, an ODS that agrees to do network recruiting and retention is expected to engage in credentialing and recredentialing for its particular network. However, it is also possible that an ODS may want to perform credentialing and recredentialing for all or some portion of a carrier's network that is not the ODS' network.

Proposed N.J.A.C. 8:38B-4 sets forth the standards for contracts between most ODSs and carriers (referred to in the proposed rules as management agreements). The subchapter applies to all contracts between carriers and ODSs and establishes standards for management agreements that are similar in many respects to the standards for primary and secondary contracts at N.J.A.C. 8:38-15 and 8:38A-4.15. However, the proposed rules attempt to clarify those elements that are necessary for the management agreement to assure that the rights of the providers and covered persons are adequately protected, without requiring some of the same detail that may otherwise be required for a provider agreement or a contract for a health benefits plan. The rules establish additional provisions that the Department believes are appropriate for purposes of more clearly delineating the rights and obligations of the carrier and the ODS. The rules also make it clear that there are certain provisions that the Department will not approve of if set forth in a management agreement. Because of the possible variations in the nature of the relationship between an ODS and a carrier, certain rules of the proposed new subchapter are applicable to the management agreement only if the ODS is engaging in certain functions. Thus, the subchapter establishes rules that are applicable to all management agreements, as well as rules that are applicable to a management agreement based upon the functions to be performed by the ODS on behalf of the carrier.

Proposed N.J.A.C. 8:38B-5 sets forth the standards for provider agreements. The proposed new subchapter standards are substantially related to those currently established for provider agreements pursuant to N.J.A.C. 8:38-15 and 8:38A-4.15. The subchapter establishes standards for provisions that the Department believes must be addressed in all provider agreements, provisions that the Department believes may be appropriate for all provider agreements, and provisions that the Department will disapprove if in any provider agreement. In addition, because the statutory rights and obligations vary among providers, generally based on whether the health care provider is a health care professional, a hospital, another type of health care facility or ancillary provider, the rules set forth standards for certain provisions that are specific to the category of provider agreement at issue. As always, it must be noted that the Department's review of provider agreements and management agreements focuses on whether the contract meets the standards of the Act and specific rules promulgated pursuant thereto; approval of one of these types of contracts by the Department is not an indication that the Department believes the contract is "perfect," nor does the Department's review warrant that the contract meets all of the legal requirements for contract under other applicable law.

The Appendix to proposed new Chapter 38B contains nine exhibits. Exhibit 1 is the proposed schedule of fines. Exhibit 2 is the application checklist to be submitted with all applications. Exhibit 3 is the application cover sheet, which includes a certification that the

individual submitting the application is authorized to do so on behalf of the applicant, and that the information contained in accurate and complete. Exhibit 4 is the consent form accepting New Jersey jurisdiction. Exhibit 5 is the form for appointing the Commissioner of Health and Senior Services as the company's attorney for service of process. Exhibit 6 is an affidavit stating that the ODS is not accepting financial risk. Exhibit 7 is a biographical affidavit. Exhibit 8 includes tables to be used to provide details regarding networks. Finally, Exhibit 9 sets forth some examples that DHSS believes may be helpful in discerning who is an ODS, and when the ODS should apply for certification or licensure.

As the Department has provided a 60-day comment period on this notice of proposal, this notice is excepted from the rulemaking calendar requirements, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The primary intent of the Act, and the proposed new rules, is to heighten the accountability of those entities engaged in the delivery or allocation of health care services to New Jersey's citizens, and the financing of those services. While this heightened degree of accountability is meant to be in addition to, not in lieu of, the accountability of carriers, which are the entities that ultimately make the promise to policyholders and others covered under policies to pay benefits or provide services in exchange for the payment of premium, the Act recognizes the realities of the health care and health insurance markets, particularly as they interrelate in managed care.

Numerous organizations have developed or evolved over the years in an effort to support health care providers and carriers in dealing with managed care concepts, and to enhance the role of health care providers in the delivery of health care services under managed care arrangements. Sometimes, the provision and allocation of health care services, and even financing of health care services, are partially controlled by these organizations under contract with a carrier, and not wholly controlled by the carrier, as many people believe. The Act provides direct oversight of these entities as ODSs, allowing the Department to apply the same or substantially similar standards to ODSs as apply to carriers. This should enhance the State's role in requiring availability and accessibility of contracted services, and the State's ability to monitor the quality of the services provided. The Department also believes that direct oversight will enhance the State's ability to understand the relationships of ODSs and carriers with one another, gauge the trends related to managed health care delivery and financing, assess the core reasons for certain problems that arise in the system, and more effectively address those problems from multiple points of contact.

Economic Impact

The economic impact that these proposed new rules may have will vary from one ODS to another. However, the economic impact probably will be moderately to substantially adverse for most ODSs, at least initially. The most predictable cost will be the filing fees, set forth in the proposal; however, even the actual filing fee due will depend upon the particular functions the ODS intends to perform. The proposed new rules establish a minimum initial application filing fee of \$1,000, with a maximum filing fee of \$5,000 for those ODSs seeking certification and \$2,500 for those ODSs seeking licensing, with fees varying in between the minimum and maximum based on a proposed schedule related to the functions the ODS elects to perform in addition to the provision of health care services delivery. (For instance, an ODS that wants to

perform network management functions would submit an additional \$1,000 with the application.) Over time, ODS will incur costs associated with certification renewals, and possibly certification modifications as well. Schedules of fees related to these matters are also set forth in the proposed new rules. ODSs may incur costs related to preparation of the application(s), depending upon the particular resources of the ODS. For instance, some ODSs may elect to use the services of consultants or legal firms in the preparation and submission of their filings, as well as on-going correspondence with the Department; other ODSs may not perceive the need for such services, having professionals within their organizations able to perform the necessary services in support of the application and day-to-day operations already. Some ODSs may incur costs related to other reporting or recordkeeping requirements, though by and large, this will depend upon the functions they choose to be certified for, and the allocation of obligations between the ODSs and carriers pursuant to their contracts. The potential adverse economic impact of all of these known and possible costs may be mitigated somewhat, depending upon how ODSs market themselves, and the degree of confidence that carriers, other payors, and other entities that may utilize an ODS' services have in the ability of the ODS to perform the services it has contracted to perform.

It is possible that these proposed rules may result in some increase in health care costs. The question of how much business costs related to regulatory approvals an ODS may pass on to carriers and health care providers may be controlled by contract; however, it is likely that at least some of the costs will be passed on to other parties whether in increased fees, or reduced allocation of pooled assets, or similar such strategies, which in turn are likely to spur carriers and health care providers to seek to alter revenue sources and cost containment strategies elsewhere. Conversely, however, it is possible that some costs related to the provision of health care and health insurance may be held in check. Carriers may be able to reduce some of their administrative costs as ODSs become directly accountable to State agencies, and the State may be in a better position to help resolve certain problems in a more cost effective manner, given more direct access to ODSs.

Federal Standards Statement

The Department is not aware of any Federal law that regulates any entity that may be an ODS when the entity is acting as an ODS, nor of any Federal law that regulates carriers and their subcontractors with respect to the activities and functions governed by the Act and to be regulated by these proposed new rules. Thus, a Federal standards analysis is not required.

Jobs Impact

The Department anticipates that there may be an modest increase in jobs as a result of the proposed new rules, primarily related to regulatory compliance, and business-to-business marketing.

Agriculture Industry Impact

The proposed new rules will have no impact on the agriculture industry.

Regulatory Flexibility Analysis

The proposed new rules will have an impact upon at least some businesses that are small businesses, as that term is defined in the Regulatory Flexibility Act at N.J.S.A. 52:14B-16 et

seq., in that some entities are likely to be resident in New Jersey, employ fewer than 100 people full-time, and not dominant in their industry. Accordingly, the Department is providing a regulatory flexibility analysis. In addition, the proposed new rules create new recordkeeping and reporting requirements, varying somewhat based on the specific functions that the regulated entities elect to perform, including submission of initial and renewal applications, and applications to amend certification if the ODS intends to change some functions, or geographic service areas, as well as providing the Department with information regarding certain changes in the status of the ODS, such as addition, deletion or substitution of contracted carriers. While the proposed new rules do not require it necessarily, some ODSs may utilize professional services, such as those of consultants, legal firms, and information systems management firms, specifically for the purposes of comply with these proposed rules. For instance, an ODS might find such services appropriate for purposes of completing the application for certification, and for tracking and monitoring certain aspects of network capacity and carrier enrollment. The Department cannot predict what the capital costs might be for any ODS, but notes that most entities that may be ODSs at this time are already engaged in business with carriers, and incur the costs of performance under contract some of the same costs that may now result from regulation. The primary cost that all ODSs will incur that they have not to date is the application fee, which, as proposed, will be at least \$1,000. The application fee may increase for an ODS, depending upon the functions for which the ODS elects to be certified, though the fees proposed will not exceed \$5,000 for an ODS seeking certification, of \$2,500 for an ODS seeking a license. A similar fee structure (flat cost, plus an added cost per function, subject to established ceilings) applies for renewal applications as well.

The proposed new rules do not provide regulatory flexibility based on the size of any affected business, primarily because the statute does not provide that the standards applicable to ODSs apply differentially based on the size of the ODS involved. Rather, the proposed new rules apply different standards to ODSs based on the functions that an ODS has stated it will perform. Because it is probable that most smaller ODSs will perform fewer functions than larger ODSs, it is probable that smaller ODSs will have to meet fewer standards (and perhaps incur fewer or lower related costs) than larger ODSs will have to meet. However, whenever an ODS that qualifies as a small business performs the same functions as an ODS that is not a small business, both ODSs will be held to the same standards for purposes of certification; the standards for delivery of health care services and protections for consumers of health care services do not vary because of the size of the ODS.

Smart Growth Impact

The proposed new rules will have no impact upon the achievement of smart growth and implementation of the State Development and Redevelopment Plan.

Full text of the proposed new rules follows:

CHAPTER 38B ORGANIZED DELIVERY SYSTEMS

SUBCHAPTER 1. GENERAL PROVISIONS

8:38B-1.1 Scope

(a) This chapter shall apply to all organized delivery systems required by the Act to become a certified organized delivery system, and to all organized delivery systems required by the Act to become licensed, except where the language of the chapter clearly indicates otherwise. A non-exhaustive list of examples of entities that are subject to this chapter is set forth in Exhibit 9 of the Appendix to this chapter, incorporated herein by reference.

(b) This chapter shall apply to all carriers offering health benefits plans, except where the language of the chapter clearly indicates otherwise.

8:38B-1.2 Definitions

The following words and terms, as used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Act" means P.L. 1999, c.409; as codified, N.J.S.A. 17:48H-1 et seq., enacted January 18, 2000, and any subsequent amendments.

"Affiliate" means a person that directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, an organized delivery system.

"Basic organizational documents" means the articles of incorporation, articles of association, partnership agreement, management agreement, trust agreement, or other applicable documents as appropriate to the form of business entity involved, and all amendments to such documents.

"Business subject to the Act" means activities performed by an ODS in accordance with a contract with a carrier related to the provision of health care services under one or more health benefits plans.

"Carrier" means an insurer authorized to transact the business of health insurance as defined at N.J.S.A. 17B:17-4, a hospital service corporation authorized to transact business in accordance with N.J.S.A. 17:48-1 et seq., a medical service corporation authorized to transact business in accordance with N.J.S.A. 17:48A-1 et seq., a health services corporation authorized to transact business in accordance with N.J.S.A. 17:48E-1 et seq., or a health maintenance organization authorized to transact business pursuant to N.J.S.A. 26:2J-1 et seq.

"Case management" means the identification and tracking of the medical condition and medical needs of a carrier's covered person in consultation with health care providers in order to assist in the provision of coordination of health care services and continuity of care.

"Certified organized delivery system" or "CODS" means an ODS that is compensated on a basis that entails no assumption of financial risk, or the assumption of a de minimus financial risk, as established by N.J.A.C. 11:22- 4, so as not to require the ODS to become licensed under the Act, but rather, to become certified in accordance with the Act.

"Contract" means, in reference to a contract between an ODS and a carrier or an ODS and a health care provider or other subcontractor engaged in the provision of delivering or allocating health care services, the document representing the core agreement between the parties and all

appendixes, amendments, addenda, codicils, manuals or other documents collateral thereto, whether or not specifically incorporated within the contract.

"Control" means, when referring to an ownership interest in or by an organized delivery system or an affiliate, ownership existing in any natural or other legal person through voting securities, contract or otherwise, such that the person has the authority to direct or cause the direction of the management and/or policies of the organized delivery system that is the subject of certification or licensing, or of an affiliate of such organized delivery system.

"DHSS" means the Department of Health and Senior Services.

"DOBI" means the Department of Banking and Insurance.

"Financial risk" means financial risk as that term is defined by DOBI in accordance with N.J.A.C. 11:22-4.

"Health benefits plan" means a contract or policy that pays or provides coverage for hospital or medical services, or payment for expenses therefor, and which is delivered or issued for delivery in this State by or through a carrier. The term "health benefits plan" includes Medicare supplement coverage, risk contracts with Medicare to the extent not otherwise prohibited by Federal law, and any other policy or contract not specifically excluded by statute or this definition. The term "health benefits plan" specifically excludes the following policies or contracts: accident only, credit, disability, long-term care, CHAMPUS supplement coverage, coverage arising out of a workers' compensation or similar law, automobile medical payment insurance, personal injury protection insurance issued pursuant to N.J.S.A. 39:6A-1 et seq., or hospital confinement indemnity coverage.

"Licensed organized delivery system" or "LODS" means an ODS that is compensated on a basis that entails the assumption of financial risk by the ODS, other than a de minimus financial risk, as established by N.J.A.C. 11:22-3, and that is therefore required to become licensed in accordance with the Act.

"Licensed or otherwise authorized" means licensed or certified by a jurisdiction having legal authority pursuant to statute to issue licenses or certification for the performance of medical, dental or other health care services. The term "licensed or otherwise authorized" shall not include: licensing or certification of an organized delivery system or a similar organization by another state; or, authorization by the Secretary of the State of New Jersey or similar entity in another state, to form a particular type of business structure, whether or not for the performance of, or delivery of, health care services.

"Managed care plan" means a health benefits plan that integrates the financing and delivery of appropriate health care services to covered persons by arrangement with participating providers, who are selected to participate on the basis of explicit standards, to furnish a comprehensive set of health care services and financial incentives for covered persons to use the participating providers and procedures provided for in the plan.

"Management agreement" means the contract between a carrier and a CODS or LODS, except as noted at N.J.A.C. 8:38B-4.1.

"Organized delivery system" or "ODS" means an entity with defined governance that contracts with a carrier to provide or arrange for the provision of one or more types of health care services to covered persons under a carrier's health benefits plan(s), whether under the base policy or a rider thereto, or that provides services that effect the delivery of one or more types of health care services, the quality or quantity of one or more types of health care services delivered, or the payment of benefits under a carrier's health benefits plan for one or more types

of health care services received. The term "ODS" does not include a health care professional licensed or authorized to render professional services pursuant to Title 45 of the New Jersey Statutes, or similar laws in the jurisdiction in which the health care professional renders services; or, a health care facility licensed or authorized in accordance with Title 26 of the New Jersey Statutes, or similar laws in the jurisdiction in which the health care facility provides services.

"Participating provider" means a provider that, under contract or other arrangement acceptable to the DHSS with the carrier, the carrier's contractor or subcontractor, has agreed to provide health care services or supplies to covered persons in the carrier's managed care plan(s) for a predetermined fee or set of fees.

"Primary care provider" or "PCP" means an individual participating provider who supervises, coordinates and provides initial and basic care to members and maintains continuity of care for the members.

"Provider" means a physician, other health care professional, health care facility or any other person who is licensed or otherwise authorized to provide health care services within the scope of his or her license or authorization in the state or jurisdiction in which the health care services are rendered.

"Provider agreement" means the contract between a CODS or LODS and a provider, or between two or more ODSs.

"Utilization management" means a system for reviewing the appropriate and efficient allocation of health care services under a health benefits plan according to specified guidelines, in order to recommend or determine whether, or to what extent, a health care service given or proposed to be given to a covered person should or will be reimbursed, covered, paid for, or otherwise provided under the health benefits plan. The system may include: preadmission certification, the application of practice guidelines, continued stay review, discharge planning, preauthorization of ambulatory care procedures and retrospective review.

8:38B-1.3 CODS: compliance time frames

(a) Except as (b) below applies, no ODS required to become a CODS in accordance with N.J.A.C. 8:38B-2.1 shall execute or renew a contract with a carrier on or after (the effective date of this chapter) as a CODS unless the ODS has filed a complete application for certification in accordance with the requirements of this chapter, and the application has been approved by DHSS.

(b) If an ODS required to become a CODS has contracts in effect on the (effective date of this chapter) and submits a completed application for certification within 90 days following (the effective date of the chapter), then nothing in this chapter shall be construed to operate to impair the terms of the contracts in effect on (the effective date of this chapter) for up to 24 months or the first renewal of the contracts occurring 90 days after (the effective date of this chapter), whichever is earlier.

1. An ODS that filed a preliminary application with DHSS pursuant to Bulletin 2000-17, issued jointly by DHSS and DOBI on December 26, 2000, shall be deemed to be in compliance with (b) above if the ODS submits the fee for filing an application set forth at N.J.A.C. 8:38B-2.9, and any information required by this chapter not previously submitted with the preliminary application (for instance, flow charts and summary tables) within 90 days following the effective date of this chapter.

8:38B-1.4 CODS: suspension or revocation of a certification

(a) DHSS may suspend or revoke the certification of a CODS upon a finding that:

1. The ODS is operating in contravention of its basic organizational documents;
2. The ODS is unable to fulfill its obligations to the carriers with which it has contracted;
3. The continued operation of the ODS would be detrimental to the carriers with which it has contracted to provide services, or hazardous to the health and welfare of the covered persons of the carriers with which the ODS has contracted to provide services;
4. The ODS is unable to maintain the standards applicable to it in this chapter;
5. The ODS has failed to comply with the applicable provisions of N.J.S.A. 26:2S-1 et seq., and rules promulgated pursuant thereto;
6. The ODS has failed to provide the services for which it was certified, has provided services in contravention of the contract or contracts filed with DHSS, or the ODS has provided services pursuant to management agreements or provider agreements for which the ODS has not been approved;
7. The ODS has failed to comply with the Act, or with other applicable law not otherwise enumerated in (a)1 through 6 above; or
8. There are other grounds that DHSS believes reasonably warrant suspension or revocation of the certification.

(b) When DHSS orders a suspension or revocation of a certification, it shall do so in writing setting forth the grounds for the suspension or revocation, and setting forth a time for a hearing to be conducted in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

1. The suspension or revocation shall be effective no later than 10 days following the date of the written notice, but the effective date may be stayed until a final decision is issued following a hearing upon the written request of the ODS, unless DHSS determines in writing that a stay of the suspension or revocation would be hazardous to the carrier(s) with which the ODS does business, or the covered persons of such carrier(s).

2. The ODS may waive its right to a hearing by providing affirmative notice of such a waiver to the agency issuing the notice of the suspension or revocation.

3. Unless the ODS waives its right to a hearing, the ODS shall submit with its request for the hearing, a written response to the notice of suspension or revocation either accepting or denying the findings set forth in the notice of suspension or revocation, and with respect to denials of the findings, specifying the factual and legal bases on which the ODS relies for denial of the findings.

(c) If an ODS' certification is revoked, the ODS shall submit to DHSS within 15 days of the date of notice of the revocation, a plan for the winding-up of the ODS' affairs, and the ODS shall conduct no further business subject to the Act regardless of whether the revocation is stayed pending a hearing.

1. The ODS shall not engage in any business subject to the Act that is in addition to the business in which it was engaged on the date of the order of revocation, except that, if DHSS stays the revocation pending the outcome of a hearing, the ODS may provide services to new covered persons of the carrier(s) with which it is contracted on the date of the order of revocation, unless the order specifies otherwise.

2. The ODS' plan to wind-up its business subject to the Act shall specify the means by which the ODS shall assure continuity of care for a carrier's covered persons, unless the order of revocation finds that the provision of continuity of care by the ODS would be hazardous to the carrier or the carrier's covered persons.

3. The ODS may request in writing that DHSS approve the ODS to continue engaging in activities with carriers, which activities are not otherwise essential to the winding up of the ODS' business subject to the Act and DHSS may grant such a request in its discretion.

4. DHSS may permit or require an ODS to continue to engage in activities that are essential to the winding-up of an ODS' business subject to the Act, or additional activities, if DHSS determines in writing that the performance of such activities are in the best interests of the covered persons of one or more carriers with which the ODS has a contract.

(d) DHSS shall provide written notice to carriers contracted with an ODS of the suspension or revocation of the ODS' certification, and the proceedings therefor, except that DHSS shall be obligated to notify only those carriers of which DHSS has specific notice of a contract with the ODS.

1. DHSS shall not be obligated to notify any other party doing business with the ODS of the suspension or revocation of the certification of the ODS.

8:38B-1.5 LODS: recommendation to suspend or revoke a license

DHSS may recommend that DOBI suspend or revoke the license of an LODS for the reasons set forth at N.J.A.C. 8:38B-1.4(a).

8:38B-1.6 CODS: penalties

(a) DHSS may assess a penalty of not less than \$250.00 nor more than \$10,000 against a CODS for each day that the CODS is in violation of the Act or rules promulgated pursuant thereto, in lieu of, or in addition to, suspension or revocation of a certification.

(b) DHSS shall not assess a penalty without providing written notice of the penalty, specifying the reasons therefor, and providing the ODS an opportunity to request a hearing pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Hearing Rules, N.J.A.C. 1:1.

1. DHSS may, upon the request of the ODS, postpone the effective date of the penalty pending the request for a hearing, or until the final decision forthcoming from the hearing.

2. If an ODS requests a hearing, the ODS shall set forth in its request for a hearing all factual and legal bases upon which the ODS disputes the findings set forth in the notice of penalty assessment.

(c) The amount of fine associated with a first offense, without documented harm, is calculated by multiplying \$250.00 per violation by the known number of days during which the violation occurred, but the amount of fine associated with each subsequent offense of the same type as the first offense, without documented harm, is calculated based on the amount of time that has elapsed between the subsequent offense and the immediately preceding offense of the same type, which number is then multiplied by the number of days during which the violation occurred, as follows:

1. If the subsequent offense occurred within less than 12 months of the first or previous offense, then the dollar multiplier is determined by multiplying \$250.00 (and each subsequent result) by three, to a maximum of \$10,000.

2. If the subsequent offense occurred 12 and up to 24 months after the first or previous offense, then the dollar multiplier is determined by multiplying \$250.00 (and each subsequent result) by two and a half, to a maximum of \$10,000.

3. If the subsequent offense occurred 24 and up to 36 months after the first or previous offense, then the dollar multiplier is determined by multiplying \$250.00 (and each subsequent result) by two, to a maximum of \$10,000.

4. If the subsequent offense occurred 36 or more months after the first or previous offense, then the dollar multiplier is determined by multiplying \$250.00 (and each subsequent result) by one and a half, to a maximum of \$10,000.

5. Where the result (and next multiplier) ends in \$.50, the amount is rounded to the next highest whole number.

6. A schedule is set forth as Exhibit 1 in the Appendix to this Chapter.

(d) Whenever there is documented harm, the dollar multiplier is increased by \$500.00; however, in no instance may the dollar multiplier exceed \$10,000, regardless of the number of times the same offense is committed within any time period, or the degree of harm associated with it.

8:38B-1.7 ODS: confidentiality of information regarding covered persons

(a) An ODS shall maintain confidentially any data or information relating to the diagnosis, treatment or health of a carrier's covered persons, or prospective covered persons, obtained from the carrier, a provider, or from the individual, and shall not disclose such information to any person except:

1. To the extent it may be necessary to carry out the purposes of the Act or this chapter, including investigation of complaints by a carrier, DOBI or DHSS, and adjudication of claims or other reimbursement by a carrier or its agent;

2. Upon the express consent of the covered person or prospective covered person, or his or her legal representative, if the covered person or prospective covered person is incapacitated or a minor;

3. Pursuant to statute or court order for the production of evidence or the discovery thereof;

4. In the event of a claim or litigation between a covered person or prospective covered person and the ODS or carrier wherein the data or information is relevant to the claim or litigation. An ODS shall be entitled to claim any statutory privilege against disclosure that a provider or carrier that furnished the information to the ODS is entitled to claim;

5. For epidemiological and outcomes research when the identity of the covered person, prospective covered person, or contractholder is protected through the use of anonymized information, as defined at N.J.S.A. 17:48H-30e; or

6. Upon the informed consent of the covered person, prospective covered person, or contractholder (but only when the contractholder is a natural person, and is providing consent solely on his or her own behalf), which consent has been obtained for research approved by an institutional review board in accordance with Federal requirements for informed consent under 21 C.F.R. 50 et seq., or 45 C.F.R. 46 et seq.

(b) DHSS and carriers shall maintain any information obtained from an ODS relating to the diagnosis, treatment or health of a covered person, or prospective covered person, confidentially to the same extent as the information is required by this subsection to be maintained confidentially by the ODS, and shall not make any public disclosure of such information.

(c) Notwithstanding (a) and (b) above, nothing in this chapter shall be construed to prohibit the collection and dissemination of data that has been aggregated and otherwise stripped of personal identifiers of former, current and prospective covered persons.

8:38B-1.8 ODS: confidentiality of submitted information

(a) DHSS shall maintain personal information contained in biographical affidavits confidentially to prevent violation of citizens' reasonable expectations of privacy in accordance with N.J.S.A. 47:1A-1. For purposes of this chapter, an affiant's name shall not be considered personal information that is confidential.

(b) DHSS shall maintain confidentially documents that are not government records, as that term is defined at N.J.S.A. 47:1A-2 of the Open Public Records Act, except that DHSS shall not deem the following information to be trade secrets or proprietary, or information that would give an advantage to competitors, if disclosed:

1. Policies and procedures developed by an ODS with respect to the functions for which the ODS is seeking certification;
2. Basic organizational documents; and
3. Explanations of information system capacities and capabilities.

8:38B-1.9 Carriers: contracts with organized delivery systems

(a) No carrier shall maintain contracts with an ODS with respect to a health benefits plan unless the ODS is certified by DHSS, or licensed by DOBI.

(b) Nothing in this chapter shall relieve a carrier from compliance with any law or regulation, except as may be specifically stated within this chapter.

SUBCHAPTER 2. CERTIFICATION AND DHSS REVIEW OF LICENSE APPLICATIONS

8:38B-2.1 CODS: who must file for certification

(a) The obligation to submit an application for certification arises when a person otherwise meeting the definition of an ODS elects to enter into contracts with one or more carriers directly, rather than solely contracting with carriers through another ODS, and the ODS assumes no financial risk under the rules adopted by DOBI at N.J.A.C. 11:22-3, or ceases to assume a financial risk under the rules at N.J.A.C. 11:22-4.

(b) The obligation to submit an application for certification arises when an ODS assuming financial risk is granted an exemption by DOBI from the licensing requirement in accordance with N.J.A.C. 11:22-4.

(c) Notwithstanding (a) above, a person otherwise meeting the definition of an ODS shall not be obligated to obtain certification if:

1. The person contracts with one or more carriers directly solely for the provision of health care services that will be performed by only the health care professionals that are

shareholders or employees of the ODS, within the scope of the health care professionals' individual licenses;

2. The person is a carrier regulated under Title 17 of the Revised Statutes, Title 17B of the New Jersey Statutes, or N.J.S.A. 26:2J-1 et seq., and amendments thereto;

3. The person is regulated by N.J.S.A. 18A:64G-1 et seq. (Medical and Dental Education Act of 1970, establishing the University of Medicine and Dentistry of New Jersey);

4. The person solely provides or arranges to provide pharmaceutical services;

5. The person solely provides or arranges to provide case management services;

6. The person solely provides employee assistance plans; or

7. The person provides the services set forth at N.J.A.C. 8:38B-2.4(a)3 through 9, but does not also provide the services set forth at N.J.A.C. 8:38B-2.4(a)1 or 2.

8:38B-2.2 CODS: general filing instructions for applications for initial certification

(a) CODS shall file applications for certification with DHSS at the following address:

Attn: ODS Certification
New Jersey Department of Health and Senior Services
Office of Managed Care
PO Box 360
Trenton, NJ 08625-0360

(b) CODS shall submit applications for certification no less than 90 days prior to the date that the CODS intends to execute its first contract with a carrier, except as N.J.A.C. 8:38B-1.3 applies.

(c) CODS shall submit applications in a paper format subject to the following conditions:

1. CODS shall submit applications in three-ring binders, labeled with the CODS' name, and numbered if more than one binder is required for the submission, with an indication of how many total binders in the series there are (for example: 1 of 2 and 2 of 2);

2. CODS shall clearly tab and segregate exhibits, presenting exhibits in the order in which the information requested is set forth at N.J.A.C. 8:38B-2.3 and 2.4, with the information required by N.J.A.C. 8:38B-2.4 following the information required by N.J.A.C. 8:38B-2.3;

3. With pages numbered;

4. With every specimen contract form generated by the CODS or by a carrier with which the CODS has contracted or intends to contract containing a unique identifier in the lower left corner of each page of the form;

5. With a completed Application Checklist, set forth as Exhibit 2 of the Appendix to this chapter and incorporated herein by reference, set forth as part of the cover to the application; and

6. With a check or money order made payable to the Treasurer, State of New Jersey, in the amount set forth at N.J.A.C. 8:38B-2.9.

(c) Every application for certification shall include a response to each item of information specified at N.J.A.C. 8:38B-2.3 and 2.4.

1. When requested information is not applicable to the CODS, the CODS shall include a page in the application package with a statement that the request is not applicable.

(d) DHSS shall not consider an application for certification to be complete unless the application at least meets the requirements of (a), (b) and (c) above.

8:38B-2.3 CODS: Part A of the application for certification

(a) Every ODS shall submit the following information:

1. A completed Application Cover Sheet, contained in Exhibit 3 of the Appendix to this chapter, and incorporated herein by reference;

2. A completed Irrevocable Consent to Jurisdiction of the Commissioners and New Jersey Courts, contained in Exhibit 4 of the Appendix to this chapter, and incorporated herein by reference;

3. A completed Appointment of Attorney for the State of New Jersey, contained in Exhibit 5 of the Appendix to this chapter, and incorporated herein by reference;

4. A completed Financial Risk Affidavit, contained in Exhibit 6 of the Appendix to this chapter, and incorporated herein by reference;

5. A copy of the ODS's basic organizational documents;

6. A copy of the ODS's executed by-laws, plan of operation, rules and regulations, or similar documents intended to regulate the conduct of the ODS's internal affairs;

7. A Biographical Affidavit, contained in Exhibit 7 of the Appendix to this chapter, and incorporated herein by reference, completed for each of the individuals who are, or are intended to be, responsible for the conduct of the affairs of the ODS, including:

i. Members of the ODS's board of directors, executive committee or other governing board or committee;

ii. The ODS's principal officers, and medical director, if applicable;

iii. Any person who owns or has the right to acquire 10 percent or more of the voting securities of the ODS;

iv. Each person who has loaned funds to the ODS for the operation of the ODS's business; and

v. Partners or members, in the case of a partnership or association;

8. A business plan, consisting of:

i. An organizational chart of the ODS;

ii. A narrative description of the ODS, its facilities, and personnel, and the health care services to be offered by the ODS to a carrier;

iii. A list of the geographical areas in which the described health care services are to be performed and approximate number of each type of provider who will provide the health care services;

iv. A description of any administrative services for which the ODS shall be responsible on behalf of the carrier;

v. A list of any affiliate of the ODS that provides services to the ODS in New Jersey and a description of any material transaction between the affiliate and the ODS;

vi. A description of any arrangements between the ODS and any other ODS or subcontractor for services associated with the provisions of health care services;

vii. A description of any reinsurance or stop loss arrangements;

viii. A plan, in the event of insolvency of the ODS, for continuation of the health care services to be provided in accordance with existing contracts and laws;

ix. A description of the means by which the ODS will be compensated under contracts with carriers; and

x. A description of the arrangement for the ODS reporting of data to the carriers and a description of the carrier's oversight responsibility;

9. A specimen copy of all provider agreements made or intended to be executed between the ODS and providers relative to the provision of health care services consistent with the standards of N.J.A.C. 8:38B-5;

i. The language of (a)9 above shall not be construed to permit any ODS to execute any provider agreements for purposes of providing services as an ODS prior to the date of approval of the ODS' certification, unless the ODS was contracted with a carrier prior to (the effective date of this chapter) and the ODS is coming into compliance with this chapter in accordance with N.J.A.C. 8:38B-1.3;

10. A specimen copy of all contracts made or intended to be executed between the ODS and any other ODS or subcontractor for services associated with the provision of health care services consistent with the standards of N.J.A.C. 8:38B-5;

11. A specimen copy of all management agreements made or to be executed between the ODS and one or more carriers, containing provisions establishing the respective duties of the ODS and carrier, and otherwise consistent with the standards of N.J.A.C. 8:38B-4.

i. The language of (a)11 above shall not be construed to permit any ODS or carrier to execute any contract for purposes of the ODS providing services as an ODS prior to the date of approval of the ODS's certification, unless the ODS was contracted with a carrier prior to (the effective date of this chapter) and the ODS is coming into compliance with this chapter in accordance with N.J.A.C. 8:38B-1.3;

12. A list of all administrative, civil or criminal actions and proceedings to which the ODS, its affiliates, or persons who are responsible for the conduct of the affairs of the ODS or affiliate, have been subject, including a statement regarding the resolution of such actions and proceedings.

i. If the ODS has had its license, certificate or other authority to operate suspended or revoked by any jurisdiction, or its application for a license, certificate or other authority refused by any jurisdiction, the ODS shall include in its application a copy of any orders, proceedings and determinations related to such refusal, suspension or revocation;

13. A list of the carriers with which the ODS has contracted or intends to execute a contract pending the approval of the application.

i. The language of (a)13 above shall not be construed to permit any ODS or carrier to execute any contract for purposes of the ODS providing services as an ODS prior to the date of approval of the ODS's certification, unless the ODS was contracted with a carrier prior to (the effective date of this chapter) and the ODS is coming into compliance with this chapter in accordance with N.J.A.C. 8:38B-1.3;

14. A list of all states in which the ODS has been or currently is doing business as described in the application; and

15. The information required pursuant to N.J.A.C. 8:38B-2.4.

(b) In addition to the requested information, the CODS shall submit the appropriate fee set forth at N.J.A.C. 8:38B-2.9, calculated for both Part A and Part B of the application.

8:38B-2.4 CODS: Part B of the application for certification

(a) An ODS shall specify the services it will deliver on behalf of one or more carriers under contract, by category, as follows:

1. Performance of one or more types of health care services;
2. Network management, including recruitment and retention;
3. Credentialing and recredentialing;
4. Utilization management development;
5. Utilization management application;
6. Utilization management appeals;
7. Member complaints;
8. Provider complaints; and
9. Continuous quality improvement.

(b) The categories of delivery of services set forth in (a) above are not necessarily mutually exclusive.

1. An ODS that delivers network management services shall be delivering the categories of services in (a)1, 3, 8 and 9 above as well with respect to the ODS' network, but shall only be required to specify network management and pay the fee therefor at N.J.A.C. 8:38B-2.9, so long as no other category of services are provided with respect to any other providers or networks outside of the ODS' network for one or more carriers.

2. If an ODS delivering network management services also performs one of the categories of services in (a)4, 5, 6 and 7 above, whether or not performance is limited to the ODS' network, the ODS shall specify the additional service(s) and the additional fee(s) therefor at N.J.A.C. 8:38B-2.9.

3. All ODSs that deliver the categories of services set forth at (a)2 through 9 above shall also be delivering services pursuant to (a)1 above, but shall only be required to specify the performance of the services at (a)2 through 9 above, as appropriate, and pay the fees therefor set forth at N.J.A.C. 8:38B-2.9.

4. An ODS may solely deliver the performance of health care services (that is, the category in (a)1 above), and shall specify this and pay the fee at N.J.A.C. 8:38B-2.9 accordingly, if that is the case.

(c) An ODS that is performing or arranging for the performance of health care services shall provide the following:

1. A list setting forth the names of all providers under contract with the ODS by county, municipality and zip code, accompanied by maps of the service area identifying the location of the participating providers by address.

i. The list shall set forth the names of all provider organizations contracted with the ODS, as well as the separate names of each hospital, health care professional and ancillary provider contracted directly with the ODS, or contracted through a provider organization.

ii. The list shall specify whether any of the health care providers or provider organizations are affiliates of the ODS.

iii. The list shall specify the types of health care services that the ODS has agreed to have performed under contract with the carrier(s);

2. The criteria that the ODS will use to assure the availability and accessibility of the services to be performed, including a description and flow chart of how emergency or urgent medical services will be available 24 hours a day, seven days a week; and

3. A completed set of tables as set forth in Exhibit 8 of the Appendix to the chapter, incorporated herein by reference.

(d) An ODS that is engaging in network management on behalf of a carrier shall submit the information set forth in (c)1 above, in addition to the following:

1. The criteria that the ODS shall use to assure the availability and accessibility of the services it will provide or arrange to provide, including, but not limited, to a demonstration of the adequacy of the number of actual providers of specific health care services that the ODS proposes to provide or arrange for the provision of in relation to the number of covered persons the ODS projects it will be servicing, which demonstration shall be consistent with the standards of N.J.A.C. 8:38B-3.5;

2. An explanation of the continuous quality improvement program(s) the ODS shall use, consistent with the requirements of (k) below;

3. An explanation of the ODS' complaint and appeal system established for providers consistent with the requirements of (j) below.

4. An explanation of the ODS' provider participation panel, consistent with the standards of N.J.A.C. 8:38-3.9 or 8:38A-4.7, as appropriate;

5. An explanation of the ODS' hearing panel for provider termination actions consistent with the standards of N.J.A.C. 8:38-3.6 or 8:38A-4.9, as appropriate;

6. An explanation of the ODS' procedures for maintenance of records that include any information regarding the covered persons of carriers, and the criteria and process the ODS will use to maintain confidentiality of such information.

i. The ODS shall include an explanation of how a covered person may obtain information maintained by the ODS and contracted health care providers on the covered person at a cost that shall not in any event exceed costs established for release of hospital records.

ii. The ODS shall include an explanation of how the carrier may access the information maintained by the ODS and contracted health care providers on the covered person;

7. The ODS' credentialing and recredentialing standards and procedures, if any, consistent with the requirements of (e) below; and

8. If the ODS' provider agreement(s) includes one or more facilities requiring licensing and inspection, a statement as to any deficiencies and plans of correction implemented by the ODS' facilities in response to those deficiencies in the three-year period preceding the date of the application.

(e) If an ODS is engaging in credentialing and recredentialing on behalf of a carrier, whether with respect only to the ODS' contracted providers or other providers that may be contracted with the carrier directly or through another ODS, the ODS shall submit the information required in (c)1 above, and the following information:

1. A copy of the ODS' policies and procedures regarding the process and standards for credentialing, consistent with the requirements of N.J.A.C. 8:38B-3.6.

i. The policies and procedures shall demonstrate the status of the medical director with oversight of the credentialing program, including both his or her licensure status, organizational affiliation(s) (for example, is the medical director employed by the ODS or employed by the carrier), and the level of involvement of the medical director in the credentialing and recredentialing process;

2. The name of the medical director licensed to practice in New Jersey; and

3. A detailed explanation of how the ODS' functions are linked and coordinated with each of the contracted carriers' continuous quality improvement and complaint systems (or those of the carriers' other contractors, as appropriate), as required by N.J.A.C. 8:38B-3.6(a)6.

i. The detailed explanation shall include an outline of the organizational structures within the ODS and the carriers (and their contractors) that will communicate regarding the credentialing process, and the flow chart for such communication relative to both positive and negative credentialing or recredentialing outcomes, including the process for the ODS to react to requests for information regarding a specific health care professional pursuant to an inquiry or complaint.

(f) An ODS that is engaging in utilization management development on behalf of a carrier, whether for one or more types of health care services, and whether for a network the ODS manages or across a broader range of a carrier's business, shall submit the information required in (c)1 above, and the following information:

1. The ODS' policies and procedures setting forth the standards for development of protocols and guidelines, and demonstrating that its practices and procedures are consistent with N.J.A.C. 8:38B-3.7;

2. The name of the medical director(s) licensed to practice in New Jersey having oversight of the mechanism by which each carrier's participating providers may review and comment on protocols, whether he or she is employed by the ODS or the carrier(s), and if employed by the carriers, the method and degree of involvement that the medical director has with respect to protocol development, and method of assuring that comments of a carrier's participating providers are considered. The ODS shall include a descriptive flow chart of the process; and

3. A copy of the protocols and guidelines developed, including any instructions on use and deviations from the protocols established.

(g) An ODS that is performing utilization management on behalf of a carrier, whether for one or more types of health care services, and whether for a network the ODS manages or across a broader range of a carrier's business, shall submit the information required in (c)1 above and the following information:

1. The ODS' policies and procedures for utilization management, which shall demonstrate that the ODS is performing utilization management consistent with the standards of N.J.A.C. 8:38B-3.8. The ODS shall include a descriptive flow chart of the process;

2. The name of the medical director with oversight of the ODS' utilization management, a statement as to whether he or she is employed by the ODS or by the carrier(s), and if employed by a carrier, a detailed explanation of how the medical director provides oversight of the utilization management program of the ODS; and

3. An explanation of what utilization management criteria the ODS uses in making utilization management determinations, and how the utilization management criteria are generated.

(h) An ODS that engages in one or both stages of the utilization management appeal process on behalf of a carrier, whether for one or more types of health care services, and whether for a network managed by the ODS or across a broader range of a carrier's business, shall submit the information required in (c)1 above, and the following information:

1. The ODS' policies and procedures for the utilization management appeals process, which shall demonstrate that the ODS is processing and reviewing appeals consistent with the standards of N.J.A.C. 8:38B-3.9;

2. The name of the medical director with oversight of the ODS' utilization management appeal process, a statement as to whether he or she is employed by the ODS or by the carrier(s), and if employed by a carrier, a detailed explanation of how the medical director provides oversight of the utilization management program of the ODS, including a flow chart demonstrating the manner in which decisions are made and communicated between the ODS and the medical director;

3. An explanation of what utilization management criteria the ODS uses in making utilization management determinations, and how the utilization management criteria are generated; and

4. Specimen forms of the letters regarding appeal rights and decisions on appeals that will be sent to covered persons and providers.

(i) An ODS that processes complaints of covered persons on behalf of a carrier, whether for one or more types of health care services, and whether for a network managed by the ODS or a broader range of a carrier's business, shall submit the information required in (c)1 above, and the following information:

1. The ODS' policies and procedures for handling complaints from covered persons, demonstrating that the ODS' policies and procedures are consistent with N.J.A.C. 8:38B-3.12;

2. A detailed explanation, including a flow chart, of how the ODS' complaint handling functions are linked and coordinated with each of the contracted carriers' continuous quality improvement and complaint systems (or the carriers' contractors, as appropriate), as required by N.J.A.C. 8:38B-3.10;

3. An explanation of how the ODS segregates complaints among carriers as well as other clients on whose behalf complaints are being handled, if the ODS performs complaint handling on behalf of multiple clients; and

4. Specimen forms of the letters regarding a complaint and complaint resolution to be sent to a covered person and provider, if the provider has filed the complaint on behalf of a covered person.

(j) An ODS that handles complaints of providers on behalf of a carrier, whether for one or more types of services, and whether for a network managed by the ODS or a broader range of a carrier's business, shall submit the information required in (c)1 above, and the following information:

1. The ODS' policies and procedures for handling complaints from providers, demonstrating that the ODS' policies and procedures are consistent with N.J.A.C. 8:38B-3.11;

2. A detailed explanation, including a flow chart, of how the ODS' complaint handling functions are linked and coordinated with each of the contracted carriers' continuous quality improvement and complaint systems (or the carriers' contractors, as appropriate), as required by N.J.A.C. 8:38B-3.10;

3. An explanation of how the ODS segregates complaints among carriers as well as other clients on whose behalf complaints are being handled, if the ODS performs complaint handling on behalf of multiple clients; and

4. Specimen forms of the letters regarding a complaint and complaint resolution to be sent to a provider.

(k) An ODS that engages in performance of continuous quality improvement on behalf of a carrier, whether with respect to one or more health care services, and whether with respect to a network managed by the ODS or for a broader range of the carrier's business, shall submit the information required in (c)1 above, and the following information:

1. The policies and procedures of the ODS with respect to the continuous quality improvement program, demonstrating that the continuous quality improvement program meets the requirements of N.J.A.C. 8:38B-3.10;

2. A detailed explanation, including a flow chart, of how the continuous quality improvement program managed by the ODS on behalf of the carrier(s) is linked to and coordinates with the carriers' complaint systems and other continuous quality improvement components that the carrier may have in addition to that established by the ODS; and

3. The name of the New Jersey-licensed medical director with oversight of the continuous quality improvement program, a statement as to whether he or she is employed by the ODS or the carrier, and an explanation of the involvement of the medical director in the operations of the continuous quality improvement program.

8:38B-2.5 LODS: information required by DHSS in review of the licensing application

(a) An LODS shall submit information with its application for licensing consistent with the provisions of N.J.A.C. 8:38B-2.4, which supplements the requirements of Part C of Exhibit A of the Appendix to N.J.A.C. 11:22-4 by clarifying when certain information requested for Part C is and is not necessary (for example, flowcharts and descriptions of complaint processing and appeal systems would not be necessary if the LODS does not perform those functions under contract with a carrier).

(b) An LODS shall submit the fees specified at N.J.A.C. 8:38B-2.9.

8:38B-2.6 CODS: modification of certification

(a) A CODS shall submit an application to modify its certification when:

1. There is to be a change in ownership or control of the ODS, the ODS' parent, or an affiliate of an ODS that has control over the ODS;

2. The ODS wants to alter the categories of services on which its current certification is based;

3. The ODS wants to execute a contract with a carrier not included in the information for the current certification; or

4. The ODS wants to cease doing business with a carrier included in the information for the current certification.

(b) No modification to a CODS' certification shall be effective unless approved, or deemed approved, by DHSS.

(c) In order to effect a modification to its certification, a CODS shall submit a notice of the change to the information it has previously submitted at least 60-days prior to the date on which the CODS intends the event(s) on which the modification is based to become effective, specifying the following information:

1. The information being changed, including dated copies of any changed pages;

2. The reason for the change;

3. The anticipated short-term (approximately six months) and long-term (more than 12 months) impact that the change may have upon the availability and accessibility of the services the CODS has currently contracted to provide;

4. The time frame for implementation of the change, if any;

5. What procedures the CODS intends to take to avoid undue disruption in services resulting from the change, if any; and

6. The fee specified at N.J.A.C. 8:38B-2.9(f).

(d) DHSS may extend the 60-day review period for up to an additional 30 days without affirmatively disapproving the application for modification by providing written notice of the extension before the expiration of the 60-day review period, and no application for modification, nor any change on which the modification is based, shall become effective during the extension period.

(e) If the modification is disapproved by DHSS, DHSS shall set forth the disapproval in writing, specifying the reasons for disapproval of the requested modification, and the ODS shall not effect the requested change.

(f) No ODS shall construe an affirmative notice of conditional approval of a requested change as a final approval or deemed approval until the time period for affirmative disapproval has elapsed.

(g) An ODS shall not effect the modification based upon deemed approval until it provides written notice to DHSS that it intends to do so, including in the notice the date of the deemed approval.

8:38B-2.7 CODS: notice of changes to certification information

Except as set forth in N.J.A.C. 8:38B-2.6, an ODS shall provide DHSS with 30 days prior notice of changes to information contained in its certification unless 30 days' prior notice was impossible, in which event, the ODS shall provide notice of the change as soon as possible, but within no more than 30 days following the date of the change.

8:38B-2.8 CODS: renewal of a certification

(a) A certification shall expire on the third anniversary of the date of approval of the certification by DHSS, unless it is suspended or revoked prior thereto.

1. Modification(s) to a certification shall not alter the anniversary date of approval of an initial certification or a certification renewal.

(b) To renew a certification, the ODS shall file an application to renew its certification no later than 90-days prior to the date that its current certification is scheduled to expire.

1. An application received less than 90 days prior to the third anniversary date of a current certification shall be treated as an application for a new certification, and a new application fee shall be submitted in accordance with N.J.A.C. 8:38B-2.9(a), (b) and (c) in order to process the application.

2. If an ODS submits an application for renewal at least 90 days prior to the expiration of the current certification, DHSS shall postpone the expiration date of the current certification while the application review remains active, as set forth at N.J.A.C. 8:38B-2.10.

(c) The application for renewal shall:

1. Be accompanied by the fee specified at N.J.A.C. 8:38B-2.9(e), except as (b)1 above applies, in order to process the application;

2. Set forth all of the information specified at N.J.A.C. 8:38B-2.3 and 2.4, as appropriate to the functions performed by the ODS, or the application shall not be considered complete; and

3. Be submitted consistent with the requirements of N.J.A.C. 8:38B-2.2.

(d) If an application for certification is disapproved for reasons other than that the ODS must become licensed by DOBI, the ODS shall be subject to N.J.A.C. 8:38B-2.10, as if its application for certification had been denied.

8:38B-2.9 ODS: fees

(a) The fee for review of Part A of an application for initial certification shall be \$1,000.

(b) The fee for review of Part B of an application for initial certification, or review by DHSS of an application for initial licensing, shall be calculated by adding the specified fee for each category of services to be performed by the ODS:

1. Performance of health care services only: \$0;
2. Network management: \$1,000;
3. Credentialing and recredentialing: \$500.00;
4. Utilization management development: \$500.00;
5. Utilization management application program: \$500.00;
6. Utilization management appeal process: \$500.00;
7. Member complaints program: \$500.00;
8. Provider complaints program: \$500.00; and
9. Continuous quality improvement program: \$500.00.

(c) Notwithstanding (a) and (b) above, a CODS shall not be required to pay a total fee for initial certification exceeding \$5,000.

(d) Notwithstanding (b) above, an LODS shall not be required to pay a total fee to DHSS for review of the application for initial licensing exceeding \$2,500.

(e) The fee for renewal of a certification shall be equal to \$500.00 for review of Part A, plus the total amount derived by adding the specified fee for each category of services to be performed by the ODS, multiplied by .5, except that, in no instance shall a CODS be required to pay a total fee for certification renewal exceeding \$3,000.

(f) The fee for modification of a certification shall be determined by adding the sums for (f)1 through 5 below, as applicable to the modification request, except that no CODS shall be required to pay a total fee for a certification modification exceeding \$5,000:

1. For addition of one or more categories of services, the sum of the amounts specified in (b) above;
2. For addition of a carrier, \$500.00;
3. For deletion of a carrier, \$100.00;
4. For deletion of a category of service, \$100.00;
5. Change in ownership, acquisition or merger: \$500.00.

8:38B-2.10 Review of applications

(a) DHSS shall determine whether an application is disapproved as incomplete within 30 days of the date of receipt of the application, and shall notify the ODS in writing of a determination of incompleteness, specifying the items that the ODS shall submit in order to make the application complete.

1. With respect to an application for certification or an application for certification modification, the ODS may resubmit the application with the required information, annotating it as a "Resubmission following Notice of Incompleteness" without submission of any additional application fee within no more than 120 days following notice of disapproval, and the review of the application shall remain active; however, DHSS shall treat resubmission of an application at a later date as an entirely new submission, requiring submission of a new application fee, as appropriate to the type of application in question.

2. With respect to an application for certification renewal, additional information shall be submitted prior to the date of expiration of the current certification in order to maintain the application for renewal as active, and avoid payment of a new certification fee.

(b) Notwithstanding that an application may be deemed or affirmatively found complete, DHSS shall not be prohibited from requesting additional information from the ODS as may be necessary to answer questions that may arise subsequent to the deemed or affirmed determination of completeness, or pursuant to changed circumstances presented by either the ODS or one or more carriers with which the ODS contracts or proposes to contract.

(c) DHSS may disapprove an application at any time during the review process if DHSS believes that the compensation arrangement between the ODS and the carrier involves the transfer of financial risk as defined at N.J.A.C. 11:22-4, and shall notify the ODS in writing accordingly, specifying the reasons therefor.

1. If, following a hearing in accordance with (f) or (g) below it is determined, or an ODS otherwise proves to DHSS' satisfaction, that the ODS is not accepting a transfer of financial risk, notwithstanding the passage of time involved, DHSS shall reactivate review of the ODS' application without any additional application fee, except as may be necessary to reflect a change in the functions for which the ODS may desire to be certified.

(d) If the application is complete, and the compensation arrangement does not involve the transfer of risk, DHSS shall approve the application, and provide notice of approval to the ODS in writing following a determination that the information provided by the ODS demonstrates that:

1. The persons responsible for conducting the ODS's affairs are competent, trustworthy and possess good reputations, and have appropriate experience, training and education to conduct the affairs of the ODS for the purposes for which the application has been submitted;

2. The persons responsible for the provision of health care services are properly qualified;

3. The ODS has the ability to assure that health care services are appropriately available and accessible for the carrier's covered persons;

4. The forms of provider agreements that may be used by the ODS with providers meet the standards set forth in this chapter;

5. The forms of the management agreements that may be used by the ODS with carriers meet the standards set forth in this chapter;

6. The ODS has the ability to meet all of the standards established by this chapter relevant to the performance of the functions for which the ODS is seeking certification; and

7. The ODS has the ability to meet all of the standards of N.J.S.A. 26:2S- 1 et seq. relevant to the performance of the functions for which the ODS is seeking certification that are not otherwise specified in this chapter.

(e) Certification of an ODS to perform certain functions shall not be construed as certification by the ODS to perform other functions for which it may wish to contract with a carrier, but shall be limited to those functions for which the application was submitted, until such time as the ODS submits a complete application to amend its certification, and the amendment is approved or deemed approved.

1. Notwithstanding (e) above, a CODS may contract with more than one carrier for the performance of all or some portion of the functions for which the CODS has been certified, so long as all of the carriers with which the CODS contracts have received approval for such contracting, pursuant to N.J.A.C. 8:38, 8:38A and 11:4-37, as appropriate.

(f) When DHSS disapproves an application for certification modification for the reasons set forth in (c) above, or failure of the ODS to meet the standards of (d) above, the ODS may request a hearing within 30 days of receipt of the disapproval by submitting a request in writing to the Director of the Office of Managed Care, setting forth with specificity the reasons that the ODS disputes DHSS' notice of disapproval.

(g) When DHSS disapproves an application for certification for the reasons set forth in (c) above, or failure of the ODS to meet the standards of (d) above, the ODS may request a hearing within 30 days of receipt of the disapproval by submitting a request in writing to the Director of the Office of Managed Care, setting forth with specificity the reasons that the ODS disputes DHSS' notice of disapproval, but otherwise shall comply with the provisions of N.J.A.C. 8:38B-1.4(c), as if its certification has been revoked if the ODS was permitted to operate pursuant to N.J.A.C. 8:38B-1.3.

(h) When DHSS disapproves an application for certification renewal, the disapproval shall be the same as a revocation of certification, and the provisions of N.J.A.C. 8:38B-1.4 shall apply, except that a disapproval made pursuant to (a) above shall not be treated as a revocation until such time as the expiration of the current certification occurs, as specified in writing by DHSS.

SUBCHAPTER 3. FUNCTIONAL OBLIGATIONS OF AN ORGANIZED DELIVERY SYSTEM

8:38B-3.1 Carriers and CODS: mutual obligation to comply fully with certain standards

(a) If the contract between an ODS and a carrier delegates performance of one or more of the legal obligations of the carrier to the ODS, the ODS shall establish policies and procedures to perform those obligations consistent with the standards, if any, set forth pursuant to regulation for the performance of those obligations by the type of carrier(s) with which the ODS has contracted or will contract.

(b) A carrier's delegation to an ODS of performance of a legal obligation of the carrier established by statute or regulation shall not relieve the carrier of its legal obligation to assure that performance of that obligation occurs consistent with standards established by law, nor shall the delegation be construed to prevent DHSS from taking action against the carrier to enforce performance of the obligation, or for failure to assure appropriate performance of the obligation, notwithstanding that DHSS may also take action against the ODS.

(c) Notwithstanding (b) above, delegation by a carrier to an ODS of performance of a legal obligation established pursuant N.J.S.A. 26:2S-1 et seq., and rules promulgated pursuant

thereto, shall cause the ODS to be obligated to comply with N.J.S.A. 26:2S-1 et seq., and rules adopted pursuant thereto, to the same degree as the carrier may be obligated, except as may be specified otherwise in this chapter, and any action taken by DHSS to enforce the performance of the obligation, or to fine the carrier for failure to assure appropriate performance of the obligation, shall not be construed either to prevent DHSS from taking action against the ODS, or to reduce any legal obligation of the ODS to appropriately perform in accordance with the statute or rules.

8:38B-3.2 Carriers: limitations on delegation

(a) Carriers shall only delegate to a CODS the performance of those functions for which the CODS is certified.

(b) Where a certified function entails the performance of multiple duties, such as network management, the carrier may contract with the ODS to perform all of the duties relevant to that certified function, but may elect to contract for the ODS to perform only some of the duties relevant to that certified function; nevertheless, the ODS shall demonstrate that it has the capability to perform all of the required duties.

(c) Use by a carrier of an ODS' network shall not relieve the carrier of any obligation it may have regarding nondiscrimination against specified providers, inclusion of specified providers within its network(s), or accessibility of specified providers to covered persons pursuant to statute or regulation.

1. Either the carrier or the ODS may demonstrate that the carrier shall be in compliance with all applicable statutes and regulations addressing specific provider inclusion within the network, or payment of benefits for services performed by specified providers acting within the scope of their licenses whose services are otherwise covered under the terms of the carrier's health benefits plan.

8:38B-3.3 ODS: Application of statutes and regulations

(a) When an ODS contracts with an HMO to perform one or more of the functions listed in this chapter, the ODS shall comply with the standards applicable to the HMO for that function as set forth in the statutes and/or regulations applicable to HMOs, including, but not limited to, N.J.S.A. 26:2J-1 et seq., 26:2S-1 et seq., and N.J.A.C. 8:38, and all references to HMO therein shall be read to mean ODS.

(b) When an ODS contracts with carriers other than HMOs to perform one or more of the functions listed in this chapter, the ODS shall comply with the standards applicable to the non-HMO carrier for that function as set forth in the statutes and regulations applicable to that non-HMO carrier, including but not limited to, N.J.S.A. 26:2S-1 et seq., and N.J.A.C. 8:38A, and all references to carrier therein shall be read to mean ODS.

(c) When an ODS contracts with both HMOs and other carriers for the performance of one or more of the functions listed in this chapter, the ODS shall demonstrate compliance with all applicable rules specified in this chapter for both types of carriers.

1. If the ODS demonstrates to the satisfaction of DHSS that the ODS is in compliance with statutes and rules applicable to HMOs for a function, DHSS shall deem the ODS to be in compliance with the statutes and rules applicable to non-HMO carriers with respect to that function.

(d) When an ODS contracts to perform one or more of the functions listed in this chapter with respect to health benefits plans which are managed care plans and health benefits plans which are not managed care plans, the ODS shall demonstrate compliance with all applicable rules specified in this chapter for both types of health benefits plans.

1. If the ODS demonstrates to the satisfaction of DHSS that the ODS is in compliance with statutes and rules applicable to health benefits plans that are managed care plans with respect to a function, DHSS shall deem the ODS to be in compliance with the statutes and rules applicable to health benefits plans that are not managed care plans with respect to that function.

8:38B-3.4 ODS: performance of health care services

(a) In order to qualify for certification to provide or arrange for the provision of the performance of health care services only, an ODS shall:

1. Submit a statement certifying that the ODS shall not engage in the performance of any of the other functions set forth in this chapter for which certification is required;

2. Demonstrate that its contracted health care providers are credentialed, providing a description of the credentialing standards and procedures that the ODS uses;

3. Submit a statement specifying whether all contracted health care providers are required to become participating providers with all carriers with which the ODS contracts, for all products, or whether a health care provider may limit participation; and

4. Submit a statement that the ODS shall provide written notice to DHSS no later than 10 business days following the date that the ODS alters the types of health care services the performance of which the ODS provides or arranges to provide under contract with one or more carriers.

(b) In order to qualify for certification to provide or arrange for the provision of the performance of health care services and one or more other categories of services, as set forth at N.J.A.C. 8:38B-2.4(a), the ODS shall comply with (a)2 through 4 above, in addition to the standards applicable to the other categories of services to be provided.

8:38B-3.5 ODS: network management

(a) In order to qualify for certification to perform network management, an ODS shall comply with the requirements of N.J.A.C. 8:38B-3.4(b), and shall perform the following duties, meeting the standards of this section:

1. Recruiting, and maintenance of provider relations systems, in order to assure constant network adequacy with respect to the categories of providers to be included in the ODS' network;

2. Implementation and maintenance of a provider participation panel for the ODS' network;

3. Implementation and maintenance of a credentialing and recredentialing mechanism for the ODS' network;

4. Implementation and maintenance of a provider notice and termination hearing mechanism for the ODS' network;

5. Implementation and maintenance of a complaint mechanism for providers in the ODS' network;

6. Designation of a medical director licensed to practice medicine in New Jersey;
and

7. Implementation and maintenance of a continuous quality improvement program for the ODS' network.

(b) With respect to network adequacy, the ODS shall assure that the network meets the standards for determining network adequacy as set forth at N.J.A.C. 8:38A-4.10 or 8:38-6 for those categories of providers in the ODS' network with respect to those services that the providers are required to render.

1. If an ODS is not arranging for the provision of the carrier's entire network, the ODS shall include a statement to this effect in its demonstration, and shall specify the providers for which the ODS is agreeing to be responsible, the geographic location for which the ODS is agreeing to be responsible, and any other limitations that may be applicable to the ODS network.

(c) An ODS shall either designate a medical director for its network who is licensed to practice medicine in New Jersey and who shall be responsible for the following functions, or the ODS shall demonstrate that the medical director of the carrier is licensed to practice medicine in New Jersey, and that the carrier's medical director shall have ultimate oversight of the ODS' network with respect to the carrier's health benefits plans, including, but not necessarily limited to, the following functions:

1. Credentialing in accordance with N.J.A.C. 8:38-4.2(a)7 or 8:38A- 4.5(c)4;
2. Oversight of professional services, staff and education in accordance with N.J.A.C. 8:38-4.2(a)1 through 4, or 8:38A-4.5(c)1 through 3 and 8:38A- 3.3(b)1;

3. Providing direction and leadership to the continuous quality improvement program in accordance with N.J.A.C. 8:38-4.2(a)5 or 8:38A-3.3(b)2;

4. Establishing policies and procedures covering all health care services to be provided through the ODS' network to covered persons in accordance with N.J.A.C. 8:38-4.2(a)6 or 8:38A-3.3(b)3; and

5. Implementing or coordinating with the carrier on a procedure that provides participating providers an opportunity to review and comment on all medical, surgical and/or dental protocols applicable to the area of practice of the provider in accordance with N.J.A.C. 8:38-4.2(a)8 or 8:38A-4.5(c)5.

(d) The ODS shall demonstrate that its provider participation panel is in compliance with either N.J.A.C. 8:38A-4.7 or 8:38-3.9.

(e) The ODS shall demonstrate that its provider termination hearing process is in compliance with either N.J.A.C. 8:38A-4.9 or 8:38-3.6.

(f) The ODS shall demonstrate that it shall comply with the standards for provider termination established at either N.J.A.C. 8:38A-4.8 or 8:38- 3.5, regardless of whether the provider is terminated from the ODS network by the ODS, or from the carrier's network by the carrier.

(g) The ODS shall demonstrate that its complaint processing system for providers is in compliance with the standards at N.J.A.C. 8:38A-4.6(b) and (e), or 8:38-3.7(b) and (e).

(h) The ODS shall demonstrate that it has a continuous quality improvement program in place, setting forth the scope of the program, and addressing at least the following:

1. The duties and responsibilities of the ODS' medical director, or the medical director of the carrier with respect to the ODS' CQI program;

2. The contractual arrangements, if any, for delegation of quality improvement activities;

3. Confidentiality policies and procedures;

4. Specification of standards of care, criteria and procedures for the assessment of the quality of services provided by the providers in the ODS' network, and the adequacy and appropriateness of health care resources utilized;

5. A system of ongoing evaluation activities, including individual case reviews as well as pattern analysis;

6. A system of focused evaluation activities, particularly for frequently performed and/or highly specialized procedures, regardless of the type of provider network, or services provided by the network;

7. A system for monitoring the ODS' network providers' response and feedback on the ODS' operations, and the providers' perceptions of the operations of the carriers with which the ODS contracts;

8. The procedures for conducting peer review activities by providers within the same discipline and area of clinical practice;

9. A system for evaluating the effectiveness of the continuous quality improvement program;

10. A system for linking the continuous quality improvement program of the ODS with the continuous quality improvement programs of the carriers with which the ODS contracts, with timely and appropriate transfer of information between the contracted parties;

11. The establishment of a multidisciplinary committee that includes representation from among the providers in the network, administrative staff of the ODS, representation by the carriers with which the ODS is contracted, and nursing staff, if the ODS has nursing staff available to it, which shall be responsible for the implementation and operations of the continuous quality improvement program, including the linkage of the program with the carrier contractors, pursuant to (h)10 above; and

12. The establishment of a system for keeping the board of directors or executive committee of the ODS informed of the continuous quality improvement activities, including at least an annual written report delineating quality improvements, performance measures used and their results, and demonstrated improvements in clinical and services quality.

(i) With respect to the continuous quality improvement program of (h) above:

1. If the ODS provides or arranges for the provision of substantially all of the services that a carrier has agreed to cover or make payment of benefits for under the carrier's health benefits plan(s), the ODS' continuous quality improvement program's monitoring of the availability, accessibility, continuity and quality of care shall include at least:

i. A mechanism for monitoring patient appointments and triage procedures, discharge planning services, linkage between all modes and levels of care and appropriateness of specific diagnostic and therapeutic procedures selected by the continuous quality improvement committee;

ii. A mechanism for evaluating all of the network providers, including health care facilities.

(1) A health care facility's internal quality assurance program shall not constitute the only assessment of patient care by the ODS; and

iii. A system to monitor both provider and covered person access to utilization management services, whether or not the ODS has agreed to perform any utilization management function for the carrier.

2. In determining if an ODS' network provides or arranges for the provision of performance of substantially all of the health care services covered under a carrier's health benefits plan(s), or for which the carrier has agreed to pay benefits under its health benefits plan(s), DHSS shall not take into consideration whether the ODS provides or makes arrangement for the provision of pharmaceutical services, behavioral health services, case management, disease management, utilization management, or durable medical equipment, but shall take into consideration whether the ODS provides or arranges for the provision of preventive and primary medical care services, specialty medical and ancillary care services, inpatient services, nursing services, and rehabilitative services.

8:38B-3.6 ODS: credentialing

(a) If an ODS agrees to perform credentialing and recredentialing activities, but either does not offer network management services, or offers network management services but wishes to perform credentialing and recredentialing activities on behalf of a carrier with respect to providers outside of the ODS' network, the ODS shall demonstrate that it meets the requirements of N.J.A.C. 8:38B-3.4(b), and the following:

1. Credentialing and recredentialing shall be under the supervision of a medical director who is a physician licensed to practice medicine in New Jersey, whether under contract with the ODS, or the carrier with which the ODS has contracted;

2. Establishment of clearly written and detailed qualifications for credentialing participating providers for each network of providers being credentialed;

3. Establishment of clearly written and detailed time frames for performing credentialing and recredentialing activities, except that in no instance shall routine recredentialing be performed less frequently than once every 24 months;

4. Establishment of a mechanism for ensuring review of provider credentials by a multidisciplinary team;

5. Establishment of a system for verification of provider credentials, recertifications, performance reviews and obtaining information about any disciplinary action against the provider available from the New Jersey Board of Medical Examiners or any other State licensing board applicable to the type of provider, and the Federal Clearinghouse established pursuant to the Health Care Quality Improvement Act, Pub.L. 99-660 (42 U.S.C. §§ 1101 et seq.), and any amendments thereto; and

6. Establishment of a system assuring that the ODS' functions are linked and coordinated with the carrier's (or the carrier's contractor's) continuous quality improvement and complaint systems.

8:38B-3.7 ODS: utilization management guidelines development

(a) In order for an ODS to be certified to perform development of UM guidelines, the ODS shall comply with the requirements of N.J.A.C. 8:38B- 3.4(b), and the following:

1. The ODS shall designate a medical director to be responsible for its UM guidelines program who is licensed to practice medicine in New Jersey; or acknowledge that its utilization management program is under the ultimate oversight of the medical director of the

carrier with respect to the carrier's health benefits plans, and the carrier's medical director is licensed to practice medicine in New Jersey;

2. The UM guidelines developed by an ODS shall:

i. Be a written plan that is reviewed at least annually, and updated as appropriate, and which specifies at least the following:

(1) The procedures to evaluate clinical necessity, access, appropriateness, and efficiency of services;

(2) The mechanisms to detect underutilization and over utilization of services; and

(3) The clinical review criteria and protocols used in decision-making; and

ii. Be based on written clinical criteria and protocols developed with involvement from practicing physicians and other licensed health care providers, and be based upon generally accepted medical standards; and

3. If an ODS is responsible for development of UM guidelines with respect to at least one health benefits plan that is a managed care plan, the ODS shall also demonstrate that the UM guidelines are developed with involvement of the participating providers of the carriers with which the ODS contracts.

8:38B-3.8 ODS: Utilization management program

(a) In order for an ODS to be certified to operate a utilization management program on behalf of a carrier, the ODS shall comply with the requirements of N.J.A.C. 8:38B-3.4(b), and:

1. Have a mechanism that ensures consistent application of review criteria and uniform decisions;

2. Develop measures for evaluating the UM guidelines and application thereof, including outcome and process measures when the carrier utilizes a gatekeeper system or practice guidelines for managed care products;

3. Comply with N.J.A.C. 8:38-8.2 and 8.3 or 8:38A-3.4(c) through (f); and

4. Comply with N.J.A.C. 8:38A-4.11(b)2.

8:38B-3.9 Utilization management appeal mechanism

(a) In order for an ODS to be certified to perform duties with respect to a carrier's utilization management appeal mechanism, the ODS shall comply with the requirements of N.J.A.C. 8:38B-3.4(b), and demonstrate that its utilization management appeal mechanism is in compliance with:

1. N.J.A.C. 8:38A-3.5, if performance will only be with respect to health benefits plans that are not managed care plans; or

2. N.J.A.C. 8:38-8.4 through 8.6 or N.J.A.C. 8:38A-4.12, if performance will be with respect to one or more health benefits plans that are managed care plans.

(b) If an ODS elects to review utilization management appeals submitted by a provider without requiring the consent of the covered person prior to reviewing the appeal, the ODS shall provide notice to the provider, at least in writing, that the review is being performed as an alternative to the required utilization management appeal process established pursuant to N.J.A.C. 8:38- 8.4 through 8.6 or 8:38A-4.12, and that if the provider wishes the standards of

N.J.A.C. 8:38-8.4 through 8.6 or 8:38A-4.12 to apply throughout the appeal process, the provider shall obtain the written consent of the covered person.

8:38B-3.10 ODS: continuous quality improvement

(a) In order for an ODS to be certified to perform continuous quality improvement on behalf of a carrier, separate and apart from any network management services that the ODS may otherwise have, the ODS shall demonstrate compliance with the requirements of N.J.A.C. 8:38B-3.4(b), and:

1. That its continuous quality improvement program for the carrier meets all of the standards set forth at N.J.A.C. 8:38B-3.3(h) and (i), if performing with respect to one or more health benefits plans that are managed care plans; or

2. That its continuous quality improvement program for the carrier meets the standards of N.J.A.C. 8:38A-3.8, if performing solely with respect to health benefits plans that are not managed care plans.

8:38B-3.11 ODS: provider complaint mechanism

In order for an ODS to be certified to perform provider complaint functions on behalf of a carrier, separate and apart from any network management services that the ODS may have otherwise, the ODS shall demonstrate that it is in compliance with the requirements of N.J.A.C. 8:38B-3.4(b), 8:38-3.7(b) or 8:38A-4.6(b).

8:38B-3.12 ODS: member complaint mechanism

In order for an ODS to be certified to perform member complaint functions on behalf of a carrier, separate and apart from any network management services that the ODS may have otherwise, the ODS shall demonstrate that it is in compliance with the requirements of N.J.A.C. 8:38B-3.4(b), 8:38-3.7(a) or 8:38A-4.6(a).

SUBCHAPTER 4. MANAGEMENT AGREEMENTS WITH CARRIERS

8:38B-4.1 Scope

This subchapter shall apply to all contracts between a carrier and a COPS or LOPS, and to all contracts between two or more ODSs, for the performance of one or more functions set forth in N.J.A.C. 8:38B-2.4(a).

8:38B-4.2 General provisions

(a) All management agreement forms shall contain the following:

1. A provision specifying that the contract and amendments thereto are subject to prior approval of DHSS and DOBI, and may not be effectuated without such approval.

i. The provision may state that the following types of amendments do not require prior approval:

(1) Amendments that are of a clerical nature;

(2) Amendments which alter numbers, be they dollar amounts, enrollment amounts or the like, without altering methodologies from which the numbers were derived; and

(3) Amendments that involve the substitution of one set of variable text for another set of variable text, if both sets of variable text were previously approved for the management agreement form;

2. A provision specifying that any sections of the contract that conflict with State or Federal law are effectively amended to conform with the requirements of the State or Federal law;

3. A provision specifying the number of days or months required by both parties to the contract to provide notice of amendments to the contract.

i. The provision regarding notice for amendments shall not in any way limit the notice required to be afforded to providers in accordance with provider agreements.

ii. The provision shall include an exception to the required notice standards to accommodate more immediate changes that may be required by State or Federal law;

4. A provision specifying the compensation arrangement between the carrier and ODS.

i. If some portion of the compensation is tied to performance, or penalties may be assessed against compensation for failure to meet performance standards, the provision shall specify performance standards for the ODS to meet, as well as possible penalties for a failure to meet performance standards.

ii. The compensation arrangement and performance standards shall not be designed to provide financial incentives to an ODS to withhold covered services that are medically necessary;

5. A provision specifying that the carrier shall have access to at least the records, management information system, and other files that the ODS may maintain relevant to the functions being performed by the ODS on behalf of the carrier.

i. The provision may state that access is limited by the parties to reasonable notice, times and places, but such limitations shall be clearly specified.

ii. Reasonable prior notice shall not exceed seven business days;

6. A provision specifying that the carrier shall have the right to inspect and audit the books and records of the ODS;

7. A provision specifying whether records relevant to the operations of the carrier, other than medical records, are the property of the carrier, or are owned jointly by the carrier and ODS;

8. A provision specifying that the contract is governed by New Jersey law with respect to business transacted in New Jersey;

9. A provision specifying the term of the contract;

10. A provision specifying termination and renewal rights and obligations of the parties.

i. The provision shall specify the reasons for which the parties may terminate the contract, including whether non-cause termination is permitted, the notice required to effect termination under the various circumstances, and the opportunity to cure deficiencies on which termination may be based, if any.

ii. The provision shall not specify a notice period of less than 60 days for non-cause terminations by either party;

11. A provision specifying that any attachments, exhibits, addendums, codicils, manuals, or similar such documents, made to the contract are incorporated within the contract, if such incorporation does not occur when such a document is first mentioned in the contract;

12. A provision specifying whether the ODS may delegate one or more of the functions it is performing on behalf of the carrier.

i. If the ODS may delegate one or more functions, the provision shall specify what notice the ODS must provide to the carrier prior to delegating a function, and what right the carrier has to reject a delegation.

ii. If the functions that may be delegated are limited, the provision shall specify which functions may and may not be delegated;

13. A provision specifying that the contract, including provider agreements between the ODS and health care providers made for the provision of services to covered persons, constitutes the entire agreement between the carrier and the ODS;

14. A provision specifying what data information shall be exchanged between the carrier and the ODS with respect to demographics and utilization patterns of the population being served, the periodicity for the exchange of such data, and whether adjustments to compensation, enrollment standards, performance standards or other capabilities will be made based on the data provided, including any procedures to be followed in order to effect any such adjustments, or discussions of such adjustments; and

15. A provision specifying the period of accounting and the information to be provided with respect to any compensation arrangement involving withholds, bonuses or performance standards.

(b) Management agreement forms may include:

1. A provision specifying that the carrier and the ODS are independent contractors as permitted by statute, regulation and/or common law.

i. The provision may specify that the carrier and ODS have no employment, partnership, joint venture, or other explicit business relationship, but shall not deny the existence of an agency relationship between the carrier and the ODS; and

2. Other provisions not specifically prohibited in accordance with this subchapter or other law.

(c) No management agreement shall contain:

1. A provision that establishes any limitation on the time period during which any party to the contract may bring suit against the other that is less than that set forth under the statute of limitation established by law;

2. A provision that establishes a unilateral right of any party to the contract to amend the contract, or that otherwise requires a party to abide by the amended terms of the contract during either a notice of termination period or a continuity of care period in the event that the one party elects to terminate the contract rather than accept an amendment by the other party.

i. The provision may allow for unilateral amendment if the amendment is required by State or Federal law;

3. A provision that requires the ODS to assure that it never charges the carrier a rate that is greater than the least amount charged to another entity with which the ODS contracts for similar services, or any other most-favored- nation type of clause;

4. A provision that limits any obligation of the carrier to provide remuneration, in accordance with the terms of provider agreements, to providers under contract with the ODS for services rendered by those providers to the carrier's covered persons in the event of the default or bankruptcy of the ODS, but this shall not prohibit a provision that allows the carrier to attempt to recoup from the ODS or its assets amounts that may have been paid to the ODS that are subsequently paid separately to the ODS' contracted providers, or other unanticipated expenses incurred as a result of the default or bankruptcy of the ODS.

i. This prohibition shall not apply to a management agreement between a carrier and LODS if DOBI is permitting the carrier to take a credit for ceding reserve liability to the LODS;

5. A provision that voids or makes voidable any provision required to be part of a provider agreement in accordance with this subchapter or other law;

6. A provision that has the effect of requiring adherence by providers with a provision that is prohibited from being a part of a provider agreement in accordance with this subchapter or other law; or

7. A provision that conflicts with any of the permissible provisions of a provider agreement that is otherwise in accordance with this subchapter or other law.

(d) A management agreement shall include the provisions of N.J.A.C. 8:38B- 4.4, 4.5, 4.6, 4.7, 4.8, 4.9 and 4.10 as appropriate to the functions that the ODS is to perform on behalf of the carrier.

8:38B-4.3 Termination

(a) In addition to complying with N.J.A.C. 8:38B-4.2(a)10, every contract shall specify which terms of the contract survive termination, and the duration of such survival.

(b) When an ODS is engaged in network management, the contract shall include a provision for the continuation of the services of the providers under contract with the ODS as necessary to comply with N.J.S.A. 26:2S-9.1 and 26:2J- 11.1, and rules promulgated pursuant thereto, as appropriate to the types of providers and the carrier.

(c) Every contract shall include a provision that specifies continued access to books and records of the ODS by the carrier for a period of time following termination of the contract at least for the purpose of collecting data that the carrier is required to report to DHSS or DOBI for any part of a calendar year in which the management agreement between the ODS and the carrier was in effect.

(d) Every contract shall include a provision that specifies an orderly transfer of carrier-owned records between the ODS and the carrier, or between the ODS and another ODS on behalf of the carrier, in the event of termination of the contract between the carrier and the first ODS.

8:38B-4.4 Network management

(a) The contract shall detail the functions that the ODS is obligated to perform on behalf of the carrier with respect to network management, including all health care services and supplies the ODS will arrange to have provided to the carrier's covered persons.

(b) The contract shall specify the factors and thresholds that obligate the ODS to expand or limit the number of providers within its network in order to assure that its network meets the requirements of N.J.A.C. 8:38-6.2 and 6.3, or 8:38-4.10, as appropriate to the type(s) of providers in, and the health care services to be offered through, the network and as appropriate to the type of carrier under contract.

(c) The contract shall specify the compensation arrangement between the ODS and the health care providers in the network.

1. The compensation arrangement shall not provide financial incentives to the providers for the withholding of covered health care services that are medically necessary.

i. An ODS shall not be precluded from using capitated payment arrangements between the ODS and a provider.

ii. Notwithstanding (c)1i above, an ODS shall not use capitation as the sole method of reimbursement to providers who provide primarily supplies rather than services.

2. The provision shall specify the process by which the ODS will make payment to providers, which shall be consistent with the standards of P.L. 1999, c.154 (Health Information Technology Act) as well as P.L. 1999, c.155, and rules promulgated pursuant thereto, including N.J.A.C. 11:22-1.

(d) The contract shall specify the utilization management standards that will apply to the ODS' network.

1. If the provision does not specify that the ODS shall assure compliance with the utilization management standards of the carrier, then the provision shall specify that the carrier adopts and takes responsibility for the utilization management standards to be used by the ODS.

(e) The contract shall specify whether the ODS is responsible for any portion of the utilization management review and appeal process, and shall detail how the ODS and the carrier interact with respect to UM and UM appeals.

(f) The contract shall specify the circumstances under which a carrier may request that the ODS remove a health care provider from participation in the network and/or the carrier's product(s), and the standards applicable to such removal, which shall be the equivalent of a termination of the provider from the carrier's network.

1. With respect to providers that are health care professionals, the contract shall specify that the carrier shall provide the ODS with sufficient advance notice of the desire to terminate the provider so that the health care professional receives at least 90 days prior notice of the termination, and the right to request a hearing, except when termination is:

i. Based on a belief of the carrier that the provider has breached the terms of the provider agreement;

ii. Based on a belief of the carrier that the provider has engaged in fraud;

iii. Based on a belief of the carrier that the provider is an imminent danger to one or more covered persons, or the health, safety or welfare of the public, based on the opinion of the carrier's medical director; or

iv. To occur on the renewal date of the provider's contract, or the anniversary date of the provider's contract, if no renewal date is specified.

2. With respect to providers that are health care professionals, the contract shall specify that the carrier shall make available to the provider, whether directly or through the ODS, a written explanation of the reason for the termination upon request, if such written explanation is not otherwise provided to the health care professional automatically.

3. The contract shall specify what criteria the ODS may request from the carrier in order to effect a termination of the provider.

4. The contract may relieve the ODS of complying with N.J.S.A. 26:2S-8 and rules promulgated pursuant thereto when the provider is terminated at the request of the carrier, so long as it is stated in the contract that providers shall be directed to the carrier in order to exercise their rights pursuant to N.J.S.A. 26:2S-8.

5. The circumstances under which a carrier may request termination of a provider shall not be based on the provider filing complaints or appeals in his or her own behalf or on behalf of a covered person, or otherwise acting as an advocate of a covered person in seeking appropriate, medically necessary health care services covered by the covered person's health benefits plan.

(g) The contract shall specify the circumstances under which the ODS may terminate a provider from its network, and the standards for notice to the carrier that the ODS shall provide prior to effecting such a termination.

1. With respect to a health care professional, the ODS shall provide the carrier with sufficient notice so that the carrier's covered persons are afforded at least 30 days prior notice of the termination of the provider, except when:

i. The ODS believes that the provider has breached the terms of the provider agreement;

ii. The ODS believes that the provider has engaged in fraud; or

iii. The ODS believes that the provider is an imminent danger to one or more covered persons, or the health, safety or welfare of the public, based on the opinion of the carrier's or the ODS' medical director.

2. The contract may relieve the carrier of any obligation to comply with N.J.S.A. 26:2S-8, and rules promulgated pursuant thereto, when the provider is terminated upon the prerogative of the ODS, so long as it is stated in the contract that providers shall be directed to the ODS in order to exercise their rights pursuant to N.J.S.A. 26:2S-8.

3. The circumstances under which an ODS may terminate a provider shall not be based on the provider filing complaints or appeals in his or her own behalf or on behalf of a covered person, or otherwise acting as an advocate of a covered person in seeking appropriate, medically necessary health care services covered by the covered person's health benefits plan.

(h) The contract shall include provisions obligating the ODS to assure that providers in the network comply with the requirements of N.J.S.A. 26:2S-9.1 and 26:2J-11.1, and rules promulgated pursuant thereto, as appropriate to the type of provider and the carrier.

1. The obligation to assure that providers comply with continuity of care requirements shall apply regardless of whether the provider is terminated at the request of the carrier, at the prerogative of the ODS, or at the option of the provider.

2. The obligation to assure that providers comply with continuity of care requirements shall apply regardless of the reason for the termination, except that the ODS and the carrier may agree that the provider shall not be permitted to continue to provide care to a covered person as if the provider were in-network if the provider has been terminated on the basis of breach, fraud or imminent danger to a covered person, or the health, safety or welfare of the public.

(i) The contract shall prohibit both the ODS and the carrier from in any way discouraging open communication between providers and the carrier's covered members regarding diagnostic

tests and treatment options, and shall specify that the ODS shall not penalize a provider based on complaints or appeals made by the provider in his or her own behalf or on behalf of a covered person, or for otherwise acting as an advocate of a covered person in seeking appropriate, medically necessary health care services covered under the covered person's health benefits plan.

(j) The contract shall require the ODS to assure that its network providers will not bill, or otherwise pursue payment from, a carrier's covered persons for the costs of services or supplies rendered in-network that are covered, or for which benefits are payable, under the covered person's health benefits plan, other than for copayments, coinsurance or deductible amounts set forth in the health benefits plan, regardless of whether the provider agrees with the amount paid, or to be paid, by the ODS or carrier, as appropriate, for the services or supplies.

(k) The contract shall require the ODS to assure that its network providers treat a carrier's members without discrimination.

1. Notwithstanding (k) above, the ODS and the carrier may agree that the ODS' network will be responsible for treatment of a limited number of the carrier's total number of covered persons, so long as the standards for the limitations are set forth in the management agreement, do not result in unfair discrimination, and the ODS is obligated to assure that its network providers abide by the limitations.

2. Notwithstanding (k) above, the ODS and the carrier may agree that a provider may limit the total number of a carrier's covered persons the provider treats, so long as the standards for the limitations are set forth in the management agreement, do not result in unfair discrimination, and the ODS is obligated to assure that its network providers abide by the limitations.

(l) The contract shall specify the obligation of the ODS to assure that its network providers, if primary care providers, make health care services available to a carrier's covered person 24 hours per day, seven days per week.

(m) The contract shall specify the obligations of the ODS with respect to implementation and maintenance of a provider complaint and appeal mechanism, and shall detail the way in which the ODS' complaint and appeal mechanism is coordinated with the carrier's continuous quality improvement program.

(n) The contract shall specify the obligations of the ODS with respect to implementation and maintenance of a provider participation panel.

(o) The contract shall specify the obligations of the ODS with respect to implementation and maintenance of a credentialing program, and shall detail the way in which the ODS' credentialing program is coordinated with the carrier's continuous quality improvement program and complaint system(s).

(p) The contract shall specify the manner in which the ODS' continuous quality improvement program and the carrier's continuous quality improvement program coordinate, the information the ODS and carrier are obligated to provide to one another, and the data that each is to collect, including details regarding the timing of reports and information transfers.

8:38B-4.5 Credentialing

(a) The contract shall specify the medical director responsible for the credentialing program, and the party with which he or she is employed or affiliated.

(b) The contract shall specify the responsibilities of the ODS and the carrier with respect to the credentialing program, including the transfer of information, and the manner in which the

ODS' credentialing program coordinates with the carrier's continuous quality improvement program and complaint system(s), and what obligation the carrier has to assure compliance by providers and other ODS' to comply with the credentialing ODS' standards.

(c) The contract shall specify the time frames for performance of credentialing and recredentialing.

(d) The contract shall specify the composition of the multidisciplinary team that will review provider credentials.

(e) The contract shall specify the verification system and standards that the ODS shall use.

8:38B-4.6 Utilization management guidelines development

(a) The contract shall detail the services that the ODS is performing on behalf of the carrier, specifying the general areas of health care services for which the UM guidelines are being developed or maintained.

(b) The contract shall specify that the ODS is obligated to assure and provide demonstration of involvement of practicing physicians and other licensed providers in the development and review of UM guidelines.

1. If the area of health care services for which UM guidelines are being developed and maintained is limited, the ODS and carrier may agree that involvement of practicing physicians and other licensed health care providers may be limited to those providers engaged in the provision of the types of health care services at issue; however, if such a limitation applies, this shall be stated in the contract with specificity as to composition of the committee(s) that the ODS will utilize to develop and review the guidelines.

(c) If one or more of the health benefits plans of the carrier with which the ODS will contract is a managed care plan, the management agreement shall specify that the ODS is obligated to establish a mechanism for providers in the carrier's network, or in the network(s) with which the carrier contracts, to review and provide comment on the UM guidelines established by the ODS and be able to demonstrate compliance with this requirement.

1. The management agreement shall specify whose responsibility it is to disseminate information to participating providers regarding the ability of participating providers to review and comment on the UM guidelines.

8:38B-4.7 Utilization management program

(a) The contract shall specify the features of the ODS' program that assure its compliance with N.J.A.C. 8:38-8.2 and 8.3 or 8:38A-3.4(c) through (f) and 4.11(b)2, as appropriate to the carrier with which the ODS is contracted, and the health benefits plans for which UM will be provided.

(b) The contract shall specify the obligation of the ODS to develop measures evaluating UM guidelines and application thereof consistent with N.J.A.C. 8:38B-3.7(a)2, to make the information obtained from the evaluations available to the carrier, and to coordinate with the carrier's continuous quality improvement program and complaint system(s).

8:38B-4.8 Utilization management appeal program

(a) The contract shall specify how the ODS will comply with N.J.A.C. 8:38A- 3.5, if performance only will be with respect to health benefits plans that are not managed care plans, or

N.J.A.C. 8:38-8.4 through 8.6 or 8:38A-4.12, if performance is with respect to one or more health benefits plans that are managed care plans.

(b) If the ODS and the carrier agree that the ODS will review UM appeals submitted by a provider without requiring the consent of the covered person, the contract shall specify this, and contain provisions requiring the ODS to notify the provider and provide information in accordance with N.J.A.C. 8:38B-3.8(b).

(c) The contract shall specify the address and telephone numbers to which covered persons and providers acting on behalf of covered persons shall be referred for purposes of pursuing a Stage 1 and Stage 2 appeal, as set forth in N.J.A.C. 8:38-8 and 8:38A-3.5.

1. Notwithstanding the address and telephone numbers specified, the contract shall specify the obligation of the ODS, when corresponding with a covered person, to always identify that the ODS is acting on behalf of the carrier.

(d) The contract shall specify the information that the ODS shall maintain for the carrier, when such information shall be reported or transferred to the carrier, and the manner in which the ODS' utilization management appeal mechanism coordinates with the carrier's continuous quality improvement program.

1. The data collected by the ODS shall be at least that information that the carrier is required to report periodically to DHSS or DOBI regarding appeals and the utilization management program.

8:38B-4.9 Continuous quality improvement program

(a) The contract shall contain provisions that assure the ODS' ability to demonstrate compliance with N.J.A.C. 8:38B-3.3(h) and (i), except that, if the ODS is agreeing to perform continuous quality improvement only with respect to health benefits plans that are not managed care plans, the contract may contain provisions that demonstrate compliance with N.J.A.C. 8:38A-3.8.

(b) The contract shall specify the composition of committees that will address continuous quality improvement activities.

(c) The contract shall specify how the ODS' continuous quality improvement program will coordinate with complaint, appeal and credentialing programs of the carrier.

(d) The contract shall specify when and how information will be transferred between the ODS and the carrier.

8:38B-4.10 Complaint mechanisms

(a) The contract shall contain provisions demonstrating the ODS' compliance with N.J.A.C. 8:38-3.7(b) or 8:38A-4.6(b) if addressing provider complaints, or N.J.A.C. 8:38-3.7(a) or 8:38A-4.6(a) if addressing complaints of covered persons.

(b) The contract shall specify the authority of the ODS to resolve complaints, and the carrier to be bound by the ODS' resolution of complaints when in favor of the covered person or provider.

(c) The contract shall specify the mechanism the ODS has in place to track and maintain records of complaints, including follow-up and the resolution of complaints, the duration for which records of complaints will be maintained, the data that the ODS will collect for the carrier, and the process for transferring information regarding complaints between the carrier and the ODS.

1. Complaint records shall be maintained for no less than four years.
2. The data to be collected shall be at least that information required for the carrier to submit reports to DHSS and DOBI.

8:38B-4.11 Issuance of contracts on approved forms

(a) No ODS or carrier shall execute a contract or an amendment to a contract for a management agreement unless the form thereof has been approved by DHSS.

(b) The following are amendments that may be effectuated without approval of DHSS:

1. Amendments that are of a clerical nature;
2. Alterations to numbers, whether dollar amounts, enrollment amounts or the like, so long as there is no alteration of the methodologies from which the numbers were derived; and
3. The application of one variable provision in lieu of another variable provision, so long as both variable provisions were approved by DHSS within the same form of management agreement.

8:38B-4.12 Review and approval of management agreements

(a) Management agreements submitted with the initial application for certification or an application for licensing shall be subject to the standards for submission, review and approval as set forth at N.J.A.C. 8:38B-2.

(b) Amendments to forms of management agreements shall be submitted to DHSS for review and approval no less than 60 days prior to the date that the ODS intends to use any amendment.

(c) DHSS shall approve or disapprove the management agreement form within 60 days of the date of receipt of the form, unless DHSS extends its review period for an additional 30 days by notifying the ODS in writing of the extension.

1. In the event that DHSS does not affirmatively approve or disapprove the form, or notify the ODS of the extension of the review period, prior to the end of the 60-day period, the form may be deemed approved.

2. Notwithstanding (c)1 above, neither an ODS nor a carrier shall effectuate any amendment to a management agreement deemed approved unless the ODS has submitted a statement in writing to DHSS that it is deeming the amended form approved in accordance with (c)1 above, stating the date of deemed approval, and that the ODS is using it accordingly.

(d) If DHSS disapproves an amendment to a management agreement, DHSS shall notify the ODS in writing, specifying the reasons for the disapproval.

(e) Failure of an ODS to respond to DHSS questions regarding a management agreement within 20 business days of the date of DHSS' written inquiry will result in DHSS suspending any further action on the submission, and the time period for approval or deemed approval being tolled.

1. In the event that DHSS determines that a submission file has become inactive, DHSS shall notify the ODS in writing of the determination, which shall effectively result in disapproval of the submission.

2. A written statement from an ODS that it is deeming an amended form to be approved in accordance with (c)1 above shall have no effect following a determination that a submission file is inactive.

(f) An ODS may reactivate review of a file determined by DHSS to be inactive at any time by submitting a statement in writing that it desires the submission to be reactivated, and in the same written notice, responding to DHSS' written inquiry issued prior to the review of the submission being suspended.

1. Notwithstanding reactivation of the review, approval of the management agreement form shall not be deemed at any time subsequent to reactivation.

SUBCHAPTER 5. PROVIDER AGREEMENTS

8:38B-5.1 Scope

This subchapter shall apply to all contracts between a CODS or an LODS and a provider for the delivery of one or more health care services to a covered person of a carrier.

8:38B-5.2 General provisions

(a) All provider agreement forms shall contain:

1. A provision specifying that the contract and amendments thereto are subject to prior approval of DHSS and DOBI, and may not be effectuated without such approval.

i. The provision may state that the following types of amendments do not require prior approval of DHSS:

(1) Amendments that are of a clerical nature;

(2) Amendments that alter numbers, be they dollar amounts, enrollment amounts or the like, without altering methodologies from which the numbers were derived; and

(3) Amendments that involve the substitution of one set of variable text for another set of variable text, if both sets of variable text were previously approved by DHSS for the provider agreement form;

2. A provision specifying that any sections of the contract that conflict with State or Federal law are effectively amended to conform with the requirements of the State or Federal law;

3. A provision specifying the number of days or months required by all parties to the contract to provide notice of amendments to the contract.

i. The prior notice period required for an ODS to provide notice to a provider shall not be less than 30 calendar days.

ii. The provision shall include an exception to the required notice standards to accommodate more immediate changes that may be required by State or Federal law;

4. A provision specifying the compensation methodology between the ODS and the provider.

i. The provision shall not provide financial incentives to the provider for the withholding of covered health care services that are medically necessary, but this shall not prohibit or limit the use of capitated payment arrangements between an ODS and a provider.

ii. To the extent that some portion of the provider compensation is tied to the occurrence of a pre-determined event, or the non-occurrence of a pre-determined event, the event shall be clearly specified, and the ODS shall include in its contracts a right of each

provider to receive a periodic accounting of the funds held, which shall be no less frequently than annually.

iii. The provision shall specify that a provider may appeal a decision denying the provider additional compensation to which the provider believes he or she is entitled under the terms of the provider agreement.

iv. Notwithstanding (a)4i above, capitation shall not be the sole method of reimbursement to providers that primarily provide supplies rather than services.

v. In no event shall the provision indicate that the compensation terms will be determined subsequent to the execution of the contract between the ODS and the provider.

5. A provision specifying that the provider's activities and records relevant to the provision of health care services may be monitored from time to time either by the ODS, the carrier, or another contractor acting on behalf of the carrier in order for the ODS or the carrier to perform quality assurance and continuous quality improvement functions;

6. A provision explaining the quality assurance program with which the provider must comply.

i. The provision shall specify whether the quality assurance program is that of the ODS and is being adopted by the carrier, is that of the carrier and is being adopted by the ODS, or is that of a separate entity and is being adopted by both the carrier and the ODS with which the provider is contracted.

ii. The provision shall specify the entity that is responsible for the day-to-day administration of the quality assurance program.

iii. The provision shall specify the entity with which the provider may lodge complaints regarding the quality assurance program, and otherwise provide information on how provider feedback regarding the operations of the ODS and carrier operations will be elicited;

7. A provision explaining the utilization management program with which the provider must comply.

i. The provision shall specify whether the utilization management program is that of the ODS and is being adopted by the carrier, is that of the carrier and is being adopted by the ODS, or is that of a separate entity and is being adopted by both the carrier and the ODS with which the provider is contracted.

ii. The provision shall explain what entity is responsible for the day-to-day operation of the utilization management program, how the provider is to comply with the UM standards, including the method for obtaining a UM decision and appealing UM decisions, and the right of the provider to have the name and telephone number of the physician denying or limiting an admission, service, procedure or length of stay.

iii. The provision shall explain how providers may receive information regarding the UM protocols and any parameters that may be placed on the use of one or more protocols.

iv. The provision shall explain how participating providers may review and provide comment on the applicable protocols for the provider's practice area.

v. The provision shall explain that the provider has the right to rely upon the written or oral authorization of a service if made by the carrier or the entity identified as being responsible for the day-to-day operations of the utilization management program, and that the services will not be retroactively denied as not medically necessary except in cases where

there was material misrepresentation of the facts to the carrier or the entity identified as being responsible for the day-to-day operations of the utilization management program, or fraud;

8. A provision explaining the rights and obligations of the provider when appealing a UM decision on behalf of a covered person, including the right to receive a written notice of the UM determination.

i. The provision shall be clear as to whether the provider must obtain consent of the covered person in order for the appeal to be reviewed in accordance with the Stage 1 and Stage 2 process as set forth at N.J.A.C. 8:38-8 and 8:38A-3.5, or whether failure to obtain consent of the covered person results in review of the appeal using a separate complaint or provider grievance process.

ii. In the event that an appeal instituted by a provider on behalf of a covered person will be entertained as a member utilization management appeal without the covered person's consent, the provision shall explain that such appeals will not be eligible for the Independent Health Care Appeals Program, established pursuant to N.J.S.A. 26:2S-11, until the covered person's specific consent to the appeal is obtained.

iii. The provision shall not limit the right of the provider to submit an appeal on behalf of the covered person to situations in which the covered person may be financially liable for the costs of the health care services;

9. A provision specifying that the contract is governed by New Jersey law;

10. A provision specifying the term of the contract.

i. Every provider agreement shall specify the date the contract is executed, which shall not be prior to the date that the ODS is first certified to operate in New Jersey, except as N.J.A.C. 8:38B-1.3 applies.

ii. The anniversary date of the contract shall be the execution date of the contract, if no anniversary date is otherwise specified;

11. A provision specifying termination and renewal rights and obligations of the parties with respect to termination and renewal;

12. A provision prohibiting providers from billing or otherwise pursuing payment from a carrier's covered person for the costs of services or supplies rendered in-network that are covered, or for which benefits are payable, under the covered person's health benefits plan, except for copayment, coinsurance or deductible amounts set forth in the health benefits plan, regardless of whether the provider agrees with the amount paid or to be paid, for the services or supplies rendered;

13. A provision establishing the obligation of the provider to be credentialed and otherwise eligible to participate in various programs (for example, Medicare or Medicaid), as appropriate.

i. The provision shall set forth the time periods for credentialing and recredentialing of providers, and the obligation of the provider to cooperate with the credentialing process;

14. A provision setting forth the provider's obligation to maintain malpractice insurance in the amount of not less than \$1,000,000 per occurrence and \$3,000,000 in the aggregate per year.

i. The provision may require that the amount of malpractice insurance must be sufficient for anticipated risk, so long as the minimum amounts of \$1,000,000/\$3,000,000 are specified;

15. A provision specifying that any attachments, exhibits, addenda, codicils, manuals, or similar such documents, made to the contract are incorporated within the contract, if such incorporation does not occur when such a document is first mentioned in the contract;

16. A provision setting forth the health care services and supplies that the provider is to render to covered persons;

17. A provision specifying that providers shall have the right and obligation to communicate openly with all covered persons regarding diagnostic tests and treatment options;

18. A provision specifying that providers shall not be terminated or otherwise penalized because of complaints or appeals that the provider files on his or her own behalf, or on behalf of a covered person, or for otherwise acting as an advocate for covered persons in seeking appropriate, medically necessary health care services covered under the covered person's health benefits plan;

19. A provision stating that the provider shall not discriminate in his or her treatment of a carrier's covered persons.

i. The provision may permit providers to limit the total number of a carrier's covered persons that the provider treats, so long as the standards for the limitations do not result in unfair discrimination and are set forth clearly in the provider agreement.

ii. The provision may permit the provider to limit the carrier's products for which the provider will be considered a participating provider, so long as the standards for the limitations are set forth clearly in the provider agreement;

20. A provision setting forth the procedures for submitting and handling of claims, including any penalties that may result in the event that claims are not submitted timely, the standards for determining whether submission of a claim has been timely, and the process for providers to dispute the handling or payment of claims.

i. Provisions addressing claims handling shall be consistent with P.L. 1999, c.154 (Health Information Technology Act) as well as P.L. 1999, c.155, and rules promulgated pursuant thereto, including N.J.A.C. 11:22-1.

ii. The provision shall specify how interest for late payment of claims shall be remitted to the provider, but in no instance shall the provision obligate the provider to request payment of the interest before the interest will be paid;

21. A provision explaining how the provider may submit and seek resolution of complaints and grievances, separate and apart from submitting complaints and grievances on behalf of a covered person, and complaints addressing compensation and claims issues.

i. The provision shall specify the time frames for resolving complaints and grievances, which shall not exceed 30 days following receipt of the complaint or grievance.

ii. The provision shall explain the right of the provider to submit complaints and grievances to the DHSS, DOBI or DHS, depending upon the issue involved, if not satisfied with the resolution of the complaint or grievance through the internal provider complaint mechanism;

22. A provision specifying that the contract, including any management agreement between the ODS and carriers, constitutes the entire agreement between the provider and the ODS; and

23. A provision setting forth the confidentiality requirements that may apply to various records, including medical records, that the parties may maintain pursuant to their contractual relationship.

(b) Every provider agreement form may contain:

1. A provision specifying that the provider and the ODS are independent contractors as permitted by statute, regulation and/or common law.

i. The provision may specify that the carrier and ODS have no employment, partnership, joint venture, or other explicit business relationship, but shall not deny the existence of an agency relationship between the ODS and the provider;

2. A provision specifying that the provider and any carriers with which the ODS may contract are independent contractors as permitted by statute, regulation and/or common law.

i. The provision may specify that the provider and carrier(s) have no employment, partnership, joint venture or other explicit business relationship, but shall not deny the existence of an agency relationship between the provider and the carrier; and

3. Other provisions not specifically prohibited in accordance with this subchapter or other law.

(c) No provider agreement form shall contain:

1. A provision that establishes any limitation on the time period during which a provider may bring suit that is less than that set forth under the statute of limitation established by law;

2. A provision that establishes a unilateral right of the ODS, acting in its own accord, or at the request of a carrier, to amend the contract, or that otherwise requires a provider to abide by the amended terms of the contract during either a notice of termination period or a continuity of care period in the event that the provider elects to terminate the contract rather than accept the amendment.

i. The provision may allow for unilateral amendment if the amendment is required by State or Federal law;

3. A provision that requires the provider to submit to arbitration, mediation or other alternate dispute resolution process either as the sole means of resolving a dispute with the ODS or carrier(s), or as an initial step in pursuing a remedy.

i. There may be a provision that allows the provider to elect to use arbitration, mediation or other alternate dispute resolution processes.

ii. There may be a provision that allows the provider and the ODS and/or carrier to agree at the time of initiation of an alternate dispute process whether the decision rendered through the process will be binding upon all parties to the process, which can then be evidenced through a separate, written agreement of the parties;

4. A provision that states or can be interpreted to mean that the provider may not appeal a utilization management determination on behalf of a covered person with the covered person's specific consent, or otherwise limits the right of the provider to dispute a utilization management determination;

5. A provision stating that the provider may not look to the carrier for payment for services or supplies rendered to a carrier's covered person in the event of default or bankruptcy of the ODS.

i. There may be a provision that specifies a process that the provider must follow in order to obtain payment from the carrier in the event of default or bankruptcy of the ODS, including subrogation or assignment of the provider's right to submit any claim against the assets of the ODS to the carrier following satisfaction of the claim by the carrier.

ii. There may be a provision that specifies that the carrier shall only be liable to the provider in accordance with the terms of the provider agreement between the provider and the ODS.

iii. This prohibition shall not apply to a provider agreement of a LODS if DOBI is permitting the carrier to take a credit for ceding reserve liability to the LODS;

6. A provision that requires a provider to participate in all of a contracted carrier's products.

i. A provision may require a provider to be a participating provider for all health benefits plans which are of a type within a carrier's line of products; for example, all health benefits plans offered with a selective contracting arrangement, all health benefits plans offered on a point of service basis, or all health benefits plans offered as a closed panel or HMO plan;

7. A provision that states or can be interpreted to mean that the provider can not dispute a reassignment or bundling of codes on a claim, or that the provider must accept any or all adjustments to a claim as payment in full when the adjustment is made as a result of the quality assurance, continuous quality improvement, utilization management, provider incentive, or similar such program;

8. A provision that states that payment to a provider with respect to a medically necessary health care service or supply will be denied if the service was not pre-certified or pre-authorized.

i. There may be a provision that allows payment to be reduced up to, but not exceeding, 50 percent of what would otherwise have been paid had pre- certification or pre-authorization been obtained for a medically necessary service, but only if the actual percentage reduction is set forth in the provider agreement;

9. A provision that states or may be interpreted to mean that a covered person lacks the ability to dispute whether a service is a covered service or whether the person was a covered person of a carrier at the time that the service was rendered;

10. A provision that requires the provider to assure that it never charges the ODS or carrier a rate that is greater than the least amount charged to another entity with which the provider contracts for similar services, or any other "most-favored-nation" type of clause;

11. A provision that requires a provider to be responsible for the actions of a non-participating provider; or

12. A provision that imposes obligations or responsibilities upon a provider that requires the provider to violate statutes or rules governing his or her license, or otherwise violate laws governing the confidentiality of patient information, in order to comply with the terms of the contract.

i. In addition, the contract shall not contain a provision that is inconsistent with laws setting forth procedures for determining whether and how specific types of confidential information may be released, including N.J.S.A. 45:14B-31 et seq.

8:38B-5.3 Termination and continuity of care standards for contracts with health care professionals

(a) Provider agreements shall specify the term of the contract, reasons for which the contract may be terminated by one or more parties to the contract, procedures for notice and

effectuation of such termination, and opportunities, if any, to cure any deficiencies prior to termination.

1. If the reason(s) for which a provider may be terminated from the ODS' network is different from the reason(s) for which a provider may be removed from participation in a carrier's panel, the contract shall so specify this.

2. If the contract permits a provider to elect not to participate in a carrier's panel without also terminating the provider agreement with the ODS, the contract shall contain a provision setting forth the standards and procedures for this.

(b) The provider agreement may specify that the contract may be terminated without cause, so long as non-cause termination is permitted by either party subject to reasonable prior notice and the terms of the provision otherwise comply with the remainder of this section.

(c) The contract shall stipulate that, when the provider's status as a participating provider in a carrier's network is being terminated, written notice shall be issued to the provider no less than 90 days prior to the date of termination, except that the 90-day prior notice requirement need not apply when the contract is being terminated upon its date of renewal, or upon its anniversary date, if no annual renewal date is specified, or is being terminated because of breach, alleged fraud, or because, in the opinion of the medical director of either the ODS or the carrier, if different, the health care professional presents an imminent danger to one or more covered persons, or the public health, safety or welfare.

1. The contract shall specify that the health care professional shall receive a written statement setting forth the reason(s) for the termination, and the procedures for obtaining such a written statement, in the event that the written notice of termination does not include a statement setting forth the reason(s) for the termination.

(d) The contract shall stipulate that the health care professional shall have the right to request a hearing following a notice that the health care professional's status as a participating provider with a carrier is being terminated, except that the contract may specify that the right to a hearing does not apply when the termination occurs on the date of renewal of the contract, or upon the contract's anniversary date, if no annual renewal date is specified, or termination is based on breach or alleged fraud, or because, in the opinion of the medical director of either the ODS or the carrier, if different, the health care professional presents an imminent danger to one or more covered persons, or the public health, safety or welfare.

(e) The contract shall specify the procedures for requesting a hearing from a carrier when a health care professional is terminated from participation in the carrier's network, which shall be consistent with the requirements of N.J.A.C. 8:38-3.6 or 8:38A-4.9, as appropriate.

(f) The contract shall specify that when a provider's status as a participating provider is terminated, or when the contract between the ODS and the provider terminates, regardless of the party initiating the termination, the provider, if a physician, shall remain obligated to provide services for covered persons in accordance with the following:

1. For up to four months following the effective date of the termination in cases where it is medically necessary for the covered person to continue treatment with the health care professional, except as (f)2 through 5 below applies;

2. In cases of the pregnancy of a covered person, through the postpartum evaluation of the covered person, up to six weeks after delivery;

3. In the case of post-operative care, up to six months following the effective date of the termination;

4. In the case of oncological treatment, up to one year following the effective date of the termination; and

5. In the case of psychiatric treatment, up to one year following the effective date of the termination.

(g) Notwithstanding (f) above, the contract may specify an exception to the requirement for the provider to continue to provide care, and for the ODS or carrier to pay for services rendered by the provider following the effective date of termination when the termination is based on breach or alleged fraud, or because, in the opinion of the medical director of either the ODS or the carrier, if different, the health care professional presents an imminent danger to one or more covered persons, or the public health, safety or welfare.

8:38B-5.4 Termination and continuity of care standards for provider agreements with hospitals

(a) Provider agreements shall specify the term of the contract, reasons for which the contract may be terminated by one or more parties to the contract, procedures for notice and effectuation of such termination, and opportunities, if any, to cure any deficiencies prior to termination.

1. If the reason(s) for which a provider may be terminated from the ODS' network is different from the reason(s) for which a provider may be removed from participation in a carrier's panel, the contract shall so specify this.

2. If the contract permits a provider to elect not to participate in a carrier's panel without also terminating the provider agreement with the ODS, the contract shall contain a provision setting forth the standards and procedures for this.

(b) The provider agreement may specify that the contract may be terminated without cause, so long as non-cause termination is permitted by either party subject to reasonable prior notice.

(c) The contract shall specify that if a hospital's status as a participating provider is terminated, regardless of who initiates the termination, or the reason for the termination, the hospital shall continue to abide by the terms of the contract for a period of at least four months from the effective date of the termination with respect to at least those covered persons enrolled with a carrier that is an HMO. The obligation shall apply to any health benefits plan underwritten by the HMO, regardless of the characterization of the health benefits plan (for example, regardless of whether the health benefits plan is for Medicare, Medicaid, a point-of-service plan, or a closed panel plan).

8:38B-5.5 Additional standards applicable to contracts with primary care providers and specialists

(a) The contract shall specify the mutual responsibility of the provider and carriers to assure 24-hour, seven-day per week emergency and urgent care coverage to covered persons, and the procedures to assure proper utilization of such coverage.

(b) The contract shall specify the obligation, if any, of the provider to acquire and maintain hospital admitting privileges.

8:38B-5.6 Additional standards applicable to contracts with hospitals

(a) The contract shall specify the obligation of the facility to follow clear procedures for granting of admitting and attending privileges, and to notify the ODS and/or carrier when such procedures change.

1. If notification must be made separately to one or more carriers, this shall be stated in the contract.

(b) The contract shall specify the admission authorization procedures for covered persons.

(c) The contract shall specify the procedures for notifying carriers when a covered person presents at emergency rooms.

(d) The contract shall specify procedures for billing and payment, schedules and negotiated arrangements.

8:38B-5.7 Third-party rights

(a) There shall be a provision specifying that the carrier is a third party beneficiary of the provider agreement, with privity of contract, and a right to enforce the provisions of the provider agreement in the event that the ODS fails to do so, except that such a provision is not required for provider agreements between a carrier and an ODS (whose shareholders are composed solely of health care providers, if the ODS is certified or seeking certification solely for the provision of the performance of health care services by its shareholders).

(b) There shall be a provision in a provider agreement between a carrier and an ODS (whose shareholders are composed solely of health care providers, if the ODS is certified or seeking certification solely for the provision of the performance of health care services by its shareholders) specifying that the providers of the ODS that participate in the network of the carrier by virtue of the contract between the carrier and the ODS are third party beneficiaries of the provider agreement, with privity of contract, and a right to enforce the provisions of the provider agreement in the event that the ODS fails to do so.

(c) There shall be a provision in a provider agreement between a carrier and an ODS (whose shareholders are composed solely of health care providers, if the ODS is certified or seeking certification solely for the provision of the performance of health care services by its shareholders) that specifies that there is privity of contract between the carrier and each of the ODS' providers that participate in the carrier's network by virtue of the contract between the carrier and the ODS, and that the carrier shall have the right to enforce the terms of the contract against such providers in the event that the ODS fails to do so.

8:38B-5.8 Use of contract addenda to reflect requirements alternating by carrier

Whenever obligations or rights under a provider agreement vary by carrier, the ODS may use addenda to an approved core contract as outlined in N.J.A.C. 8:38B-2, to set forth the variances in the obligations or rights, so long as the provisions of the contract where variances are permissible specify that addenda set forth the separate obligations or rights in separate addenda for each carrier in whose network the provider participates, and the variances have been approved by DHSS as set forth in N.J.A.C. 8:38B-5.10.

8:38B-5.9 Issuance of contracts on approved forms

(a) No ODS shall issue and execute a contract or an amendment to a contract for a provider agreement unless the form thereof has been approved by DHSS in accordance with N.J.A.C. 8:38B-5.10.

(b) The following are amendments that may be effectuated without approval of DHSS:

1. Amendments that are of a clerical nature;
2. Alterations to numbers, whether dollar amounts, enrollment amounts or the like, so long as there is no alteration of the methodologies from which the numbers were derived; and

3. The application of one variable provision in lieu of another variable provision, so long as both variable provisions were approved by DHSS within the same form of management agreement.

8:38B-5.10 Review and approval of provider agreements

(a) Provider agreements submitted with the initial application for certification or an application for licensing shall be subject to the standards for submission, review and approval as set forth at N.J.A.C. 8:38B-2.

(b) Amendments to forms of provider agreements shall be submitted to DHSS for review and approval no less than 60 days prior to the date that the ODS intends to use any amendment.

(c) DHSS shall approve or disapprove the provider agreement form within 60 days of the date of receipt of the form, unless DHSS extends its review period for an additional 30 days by notifying the ODS in writing of the extension.

1. In the event that DHSS does not affirmatively approve or disapprove the form, or notify the ODS of the extension of the review period, prior to the end of the 60-day period, the form may be deemed approved.

2. Notwithstanding (c)1 above, an ODS shall not effectuate any amendment to a provider agreement deemed approved unless the ODS has submitted a statement in writing to DHSS that it is deeming the amended form approved in accordance with (c)1 above, and using it accordingly.

(d) If DHSS disapproves an amendment to a provider agreement, DHSS shall notify the ODS in writing, specifying the reasons for the disapproval.

(e) Failure of an ODS to respond to DHSS questions regarding a provider agreement within 20 business days of the date of DHSS' written inquiry will result in DHSS suspending any further action on the submission, and the time period for approval or deemed approval being tolled.

1. In the event that DHSS determines that a submission file has become inactive, DHSS shall notify the ODS in writing of the determination, which shall effectively result in disapproval of the submission.

2. A written statement from an ODS that it is deeming an amended form to be approved in accordance with (c)1 above shall have no effect following a determination that a submission file is inactive.

(f) An ODS may reactivate review of a file determined by DHSS to be inactive at any time by submitting a statement in writing that it desires the submission to be reactivated, and in the same written notice, responding to DHSS' written inquiry issued prior to the review of the submission being suspended.

1. Notwithstanding reactivation of the review, approval of the provider agreement form shall not be deemed at any time subsequent to reactivation.

/s/ Clifton R. Lacy
Commissioner

APPENDIX
(follows)

Exhibit 1

Schedule of Fines

First offense

No documented harm: \$250

Documented harm: \$750

Subsequent offense

Less than 12 months from same prior offense:

	<i>No harm</i>	<i>Harm</i>
• 2nd:	\$750	\$1250
• 3rd:	\$2250	\$2750
• 4th:	\$6750	\$7250
• 5th+:	\$10,000	\$10,000

12 or more but less than 24 months from same prior offense:

	<i>No harm</i>	<i>Harm</i>
• 2nd:	\$625	\$1125
• 3rd:	\$1563	\$2063
• 4th:	\$3908	\$4408
• 5th:	\$9770	\$10,000
• 6th+:	\$10,000	\$10,000

24 or more but less than 36 months from same prior offense:

	<i>No harm</i>	<i>Harm</i>
• 2nd:	\$500	\$1000
• 3rd:	\$1000	\$1500
• 4th:	\$2000	\$2500
• 5th:	\$4000	\$4500
• 6th:	\$8000	\$8500
• 7th+:	\$10,000	\$10,000

36 or more months from same prior offense:

	<i>No harm</i>	<i>Harm</i>
• 2nd:	\$375	\$875
• 3rd:	\$563	\$1063
• 4th:	\$845	\$1345
• 5th:	\$1268	\$1768
• 6th:	\$1902	\$2402
• 7th:	\$2853	\$3253
• 8th:	\$4280	\$4780
• 9th:	\$6420	\$6920
• 10th:	\$9630	\$10,000
• 11th:	\$10,000	\$10,000

Exhibit 2

**New Jersey Department of Health and Senior Services
Application Checklist for ODS Certification or Recommendation for License**

Please use this checklist to complete the application package. Refer to N.J.A.C. 8:38B-2.2, 2.3 and 2.4 for more detailed instructions (applicants for license should refer also to regulations under Title 11 of the New Jersey Administrative Code). Applications should be mailed to: ODS Certification, New Jersey Department of Health and Senior Services, Office of Managed Care, P.O. Box 360, Trenton, NJ 08625-0360; street address: Health and Agriculture Building, 6th Floor, Market and Warren Streets, Trenton, NJ 08625.

**Part A
(N.J.A.C. 8:38B-2.3)**

- _____ 1. A completed Application Cover Sheet
- _____ 2. A completed Irrevocable Consent to Jurisdiction of the Commissioners and New Jersey Courts
- _____ 3. A completed Appointment of Attorney for the State of New Jersey (all applicants; for license, appoint the Commissioner of the Department of Banking and Insurance)
- _____ 4. A completed Financial Risk Affidavit (applicants for certification only)
- _____ 5. A copy of the ODS's basic organizational documents, as defined at N.J.A.C. 8:38B-1.2
- _____ 6. A copy of the ODS's executed by-laws, plan of operation, rules and regulations, or similar documents intended to regulate the conduct of the ODS's internal affairs
- _____ 7. A Biographical Affidavit completed for each of the individuals who are, or are intended to be, responsible for the conduct of the affairs of the ODS, including: i) members of the ODS's board of directors, executive committee or other governing board or committee; ii) the ODS's principal officers, and medical director, if applicable; iii) any person who owns or has the right to acquire 10 percent or more of the voting securities of the ODS; iv) each person that has loaned funds to the ODS for the operation of the ODS's business; and v) partners or members, in the case of a partnership or association
- _____ 8. A business plan consisting of:
 - i) an organizational chart of the ODS
 - ii) a narrative description of the ODS, its facilities, and personnel, and the health care services to be offered by the ODS to a carrier;
 - iii) a list of the geographical areas in which the described health care services are to be performed and approximate number of each type of provider who will provide the health care services;
 - iv) a description of any administrative services for which the ODS shall be responsible on behalf of the carrier;

- v) a list of any affiliate of the ODS that provides services to the ODS in New Jersey and a description of any material transaction between the affiliate and the ODS;
- vi) a description of any arrangements between the ODS and any other ODS or subcontractor for services associated with the provisions of health care services;
- vii) a description of any reinsurance or stop loss arrangements;
- viii) a plan, in the event of insolvency of the ODS, for continuation of the health care services to be provided in accordance with existing contracts and laws;
- ix) a description of the means by which the ODS will be compensated under contracts with carriers;
- x) a description of the arrangement for the ODS reporting of data to the carriers and a description of the carrier's oversight responsibility.

- _____ 9. A specimen copy of all provider agreements made or intended to be executed between the ODS and providers
- _____ 10. A specimen copy of all contracts made or intended to be executed between the ODS and any other ODS or subcontractor for services associated with the provision of health care services
- _____ 11. A specimen copy of all management agreements made or to be executed between the ODS and one or more carriers
- _____ 12. A list of all administrative, civil or criminal actions and proceedings to which the ODS, its affiliates, or persons who are responsible for the conduct of the affairs of the ODS or affiliate, have been subject, including a statement regarding the resolution of such actions and proceedings.
- _____ 13. A list of the carriers with which the ODS has contracted or intends to execute a contract pending the approval of the application
- _____ 14. A list of all states in which the ODS has been or currently is doing business as described in the application
- _____ 15. The appropriate fee set forth at N.J.A.C. 8:38B-2.9

Part B
(N.J.A.C. 8:38B-2.4)

- _____ 1. Services for which certification is being sought (please circle all that apply):
 - 1) Performance of one or more types of health care services delivery
 - 2) Network management
 - 3) Credentialing and recredentialing
 - 4) Utilization management development
 - 5) Utilization management application
 - 6) Utilization management appeals
 - 7) Member complaints
 - 8) Provider complaints
 - 9) Continuous quality improvement

- _____ 2. For performance of one or more types of health care services delivery:
 - _____ a) List of names of all providers by county, municipality, zip code, and services
 - _____ b) Map of the service area identifying the location of the participating providers
 - _____ c) Criteria to assure the availability and accessibility of services to be performed
- _____ 3. For network management:
 - _____ a) Demonstration of adequacy of the network for services offered in relation to population to be served consistent with standards of N.J.A.C. 8:38B-3.5
 - _____ b) Demonstration of the CQI program
 - _____ c) Demonstration of the complaint and appeal system for providers
 - _____ d) Demonstration of the provider participation panel
 - _____ e) Demonstration of the hearing panel for provider terminations
 - _____ f) Demonstration of records maintenance procedures and standards
 - _____ g) Credentialing and recredentialing standards
 - _____ h) Statement of deficiencies and POCs with respect to licensed facilities
- _____ 4. For credentialing and recredentialing:
 - _____ a) Policies and procedures, demonstrating compliance with N.J.A.C. 8:38B-3.6
 - _____ b) Designated medical director and his/her functions
 - _____ c) Explanation of linkage and coordination with the CQI and complaint systems of the carrier(s) and/or their other contractor(s), including flow chart(s)
- _____ 5. For utilization management development:
 - _____ a) Policies and procedures for developing protocols and guidelines, demonstrating compliance with N.J.A.C. 8:38B-3.7
 - _____ b) Designated medical director and his/her functions
 - _____ c) Copy of the protocols and guidelines developed, and instructions for use
- _____ 6. For performance of utilization management:
 - _____ a) Policies and procedures, demonstrating compliance with N.J.A.C. 8:38B-3.8
 - _____ b) Designated medical director and his/her functions
 - _____ c) Explanation of medical director's oversight, if employed by the carrier
 - _____ d) Explanation of the UM criteria used
- _____ 7. For utilization management appeals:
 - _____ a) Policies and procedures, demonstrating compliance with N.J.A.C. 8:38B-3.9
 - _____ b) Designated medical director and his/her functions
 - _____ c) Flow chart demonstrating communication and decision-making, if the medical director is employed by the carrier
 - _____ d) Specimens of letters regarding appeal rights and decisions on appeals to be sent to both covered persons and providers.
- _____ 8. For member complaints:
 - _____ a) Policies and procedures, demonstrating compliance with N.J.A.C. 8:38B-3.12
 - _____ b) Explanation of linkage and coordination with the CQI and complaint system of the carrier(s) and/or their other contractor(s)
 - _____ c) Explanation of how complaints are segregated among carriers (and other clients)

- _____ d) Specimens of the letters regarding complaint and complaint resolution to be sent to covered persons and providers acting on behalf of covered persons
- _____ 9. For provider complaints:
 - _____ a) Policies and procedures, demonstrating compliance with N.J.A.C. 8:38B-3.11
 - _____ b) Explanation of linkage and coordination with the CQI and complaint system of the carrier(s) and/or their other contractor(s)
 - _____ c) Explanation of how complaints are segregated among carriers (and other clients)
 - _____ d) Specimens of the letters regarding a complaint and complaint resolution to be sent to providers.
- _____ 10. For continuous quality improvement:
 - _____ a) Policies and procedures, demonstrating compliance with N.J.A.C. 8:38B-3.10
 - _____ b) Explanation of linkage and coordination with the complaint systems and other continuous quality improvement components that the carrier(s) may have
 - _____ c) Designated medical director and his/her functions

Part C
(N.J.A.C. 8:38B-2.2)

- _____ 1. Application in 3-ring binder(s), labeled with the ODS' name, and serially numbered, if necessary
- _____ 2. Application tabbed, exhibits segregated, and shown in order requested in regulations
- _____ 3. All pages numbered
- _____ 4. All specimen contracts contain unique identifier in lower left corner of each page
- _____ 5. Payment by check or money order made payable to the Treasurer, State of New Jersey
- _____ 6. No items left blank

Exhibit 3

**ORGANIZED DELIVERY SYSTEM
LICENSURE AND CERTIFICATION
APPLICATION COVER SHEET**

1. Type of Application: Licensure _____ Certification _____

2. Name of Applicant: _____

3. Physical Address of _____

Applicant: _____

4. Mailing Address: _____

5. Organizational Information

_____ Individual _____ Corporation _____ Trust
_____ Sole Proprietor _____ Partnership _____ Other

6. Provide a brief description of the services that the applicant will be providing:

7. City and State of Incorporation (if appl.) City _____ State _____

8. Federal Employer Identification number _____ - _____

9. Contact Person Information

Name: _____

Title: _____

Phone Number: _____

Toll Free Number: _____

Fax Number: _____

E-Mail Address: _____

10. Resident Status

Resident of New Jersey? Yes _____ No _____

County in which Home Office is located for NJ Residents: _____

Certification

I _____ certify that I am authorized to file this certification on
(Name and Title)

behalf of the applicant, the information set forth in the enclosed application and herein is true to the best of my information, knowledge and belief, and that the Department of Banking and Insurance and Department of Health and Senior Services may rely on the information set forth in the application and herein in determining whether to grant a license pursuant to N.J.S.A. 17:48H-1 et seq. I further certify that _____ is familiar and will
(Name and Title)

comply with the requirements set forth in N.J.S.A. 17:48H-1 et seq. and rules promulgated pursuant thereto.

Signature of Applicant

Full Legal Name (Type or Print)

Title

Date

Exhibit 4

**IRREVOCABLE CONSENT TO JURISDICTION OF THE COMMISSIONERS
AND NEW JERSEY COURTS**

THE STATE OF _____ }
COUNTY OF _____ } KNOW ALL MEN BY THESE PRESENTS:

That _____ of
(name of applicant)
_____ is filing herewith its application for
(domiciliary city and state)
a license or a certificate (circle as appropriate) to operate as an organized delivery system in the
State of New Jersey;

That, upon issuance of said license by the Commissioner of Banking and Insurance or
upon issuance of said certificate by the Commissioner of Health and Senior Services ;

_____ shall consent to the jurisdiction
(name of applicant)
of the _____ and all New Jersey courts in
(insert appropriate Commissioner)

relation to any transactions or other activity subject to regulation under N.J.S.A. 17B:48H-1 et
seq. and all other applicable New Jersey statutes or rules; and

That such consent to the jurisdiction of the Commissioner of Banking and Insurance or
the Commissioner of Health and Senior Services and the New Jersey courts shall be and
remain irrevocable for as long as _____

(name of applicant)
possesses a license from the Commissioner of Banking and Insurance or a certification from the
Commissioner of Health and Senior Services or engages in business as an organized delivery
system in or from the State of New Jersey, and until all contractual obligations in the State of
New Jersey are satisfied.

Witness our hands and the impress of the seal of said applicant, this _____
day of _____, 20_____.

(Corporate Seal--if applicable)

President
(or authorized representative)

Attest:

(Print or Type Name)

Secretary
(or authorized representative)

(Print or Type Name)

Exhibit 5

**Appointment of Attorney for the State of New Jersey
(For certification only)**

KNOW ALL MEN BY THESE PRESENTS: That the _____
(Name of ODS)

of the _____ of _____ in the _____
(Specify: city, town) (Name of city or town) (Specify: state, commonwealth)

of _____, desiring to do business in the State of New
(Name of state or commonwealth)

Jersey in conformity with the laws thereof, hereby, constitutes and appoints the Commissioner of Health and Senior Services of New Jersey, and his or her successor in office, to be its true and lawful Attorney, upon whom all original process in any action or legal proceeding against said

_____ may be served. And the said _____
(Name of ODS) (Name of ODS)
hereby stipulates and agrees that any original process against it, which is served upon said Attorney, shall be of the same legal force and validity as if served upon said

_____, and that the authority of said Attorney shall continue in
(Name of ODS)
force irrevocable so long as any liability of said _____ remains
(Name of ODS)
outstanding in New Jersey.

IN WITNESS WHEREOF, the said _____ has
(Name of ODS)
caused these presents to be subscribed by its President, and attested by its Secretary, and its corporate seal to be hereunto affixed, this _____ day of _____
20_____.

(Corporate Seal--if applicable)

President
(or authorized representative)

(Print or Type Name)

Attest:

Secretary
(or authorized representative)

(Print or Type Name)

I, _____, _____,
(Name of Officer) (Title)
an officer of _____ being duly authorized to
(Name of ODS)
provide this affidavit on behalf of _____, do
(Name of ODS)
hereby attest and affirm that _____, does not
(Name of ODS)
engage in the acceptance of the transfer of financial risk from any carrier as defined by N.J.S.A.
17:48H-1 et. seq., and rules promulgated pursuant thereto and shall not accept a transfer
of financial risk from any carrier until such time as _____
(Name of ODS)
becomes licensed by the New Jersey Department of Banking and Insurance. Further, I attest
and affirm that the compensation arrangement(s) set forth in this application do not constitute
the transfer of financial risk.

(Signature of Affiant)

Subscribed and sworn to before me this _____ of _____ 20____.

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Exhibit 7
BIOGRAPHICAL AFFIDAVIT
(To be Completed by All Applicants)
(Print or Type)

Full Name and Address of Applicant (Do not use Group Names). _____

In connection with the above-named applicant, I herewith make representations and supply information about myself as hereinafter set forth. (Attach addendum or separate sheet if space hereon is insufficient to answer any question fully.) IF ANSWER IS 'NO' OR 'NONE', SO STATE.

1. Affiant's Full Name* (Initials not acceptable). _____

2. Have you ever had your name changed?_____ If yes, give the reason for the change._____

a) Other names used at any time. _____

3. Date and place of birth. _____

4. Affiant's business address: _____

Business telephone _____

5. List your residences for the last ten (10) years starting with your current address, giving*:
DATE ADDRESS CITY and STATE

*These items may be submitted on a separate form to maintain confidentiality.

6. Education: dates, names, locations and degrees.

a) College _____

b) Graduate Studies _____

c) Others _____

7. List of memberships in professional societies and associations. _____

8. Present or proposed position with the applicant. _____

9. List complete employment record (up to and including present jobs, positions, directorates or officerships) for the past twenty (20) years, giving:

DATE	EMPLOYER and ADDRESS	TITLE
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

10. Present employer may be contacted. _____ Yes _____ No
Former employers may be contacted. _____ Yes _____ No

11. Have you ever been in a position that required a fidelity bond? _____
If any claims were made on the bond, give details _____

a) Have you ever been denied an individual or position schedule fidelity bond, or had a bond canceled or revoked? _____
If yes, give details _____

12. List any professional, occupational and vocational licenses issued by any public or governmental licensing agency or regulatory authority which you presently hold or have held in the past (state date license issued, issuer of license, date terminated, reasons for termination).

13. During the last ten (10) years, have you ever been refused a professional, occupational or vocational license by any public or governmental licensing agency or regulatory authority, or has any such license held by you ever been suspended or revoked? _____ If yes, give details

14. List any insurers, prepaid dental plans, health service corporations or health maintenance organizations, in which you control directly or indirectly or own legally or beneficially 10% or more of the outstanding stock (in voting power). _____

If any of the stock is pledged or hypothecated in any way, give details.

15. Will you or members of your immediate family subscribe to or own, beneficially or of record, shares of stock of the applicant-organized delivery system or its affiliates? _____. If any of the shares or stock are pledged or hypothecated in any way, give details. _____

16. Have you ever been adjudged a bankrupt? _____

17. Have you ever been convicted or had a sentence imposed or suspended or had pronouncement of a sentence suspended or been pardoned for conviction of or pleaded guilty or *nolo contendere* to an information or indictment, charging any felony, or charging a misdemeanor involving embezzlement, theft, larceny or mail fraud, or charging a violation of any corporate securities statute or any insurance law, or have you been a subject of any disciplinary proceedings of any federal or state regulatory agency? _____ If yes, give details _____

a) Has any company been so charged, allegedly as a result of any action or conduct on your part? _____ If yes, give details. _____

18. Have you ever been an officer, director, trustee, investment committee member, key employee or controlling stockholder of any insurer, prepaid dental plans, health service corporations or health maintenance organizations, which, while you occupied such a position or capacity with respect to it, became insolvent or was placed under supervision or in receivership, rehabilitation, liquidation or conservatorship? _____

19. Has the certificate of authority or license to do business of any insurer, prepaid dental plans, health service corporations or health maintenance organizations, of which you were an officer or director or key management person ever been suspended or revoked while you occupied such position? _____ If yes, give details. _____

Dated and signed this _____ day of _____ at _____. I hereby certify under penalty of perjury that I am acting on my own behalf, and that the foregoing statements are true and correct to the best of my knowledge and belief.

(Signature of Affiant)

State of _____

County of _____

Personally appeared before me the above named _____ personally known to me, who, being duly sworn, deposes and says that he executed the above instrument and that the statements and answers contained therein are true and correct to the best of his knowledge and belief.

Subscribed and sworn to before me this _____ of _____ 20____.

(Notary Public)

My Commission Expires _____

Exhibit 8

TABLE A: SUMMARY OF PHYSICIANS BY COUNTY
(INDICATE NUMBER OF PROVIDERS IN EACH COUNTY)

TYPE OF PROVIDER	New Jersey Counties																					
	A T L	B E R	B U R	C A M	C A P	C U M	E S S	G L O	H U D	H U N	M E R	M I D	M O N	M O R	O C E	P A S	S A L	S O M	S U S	U N I	W A R	S T A T E - W I D E
A. PRIMARY CARE PHYSICIANS																						
1. Family Practice																						
2. General Practice																						
3. Internal Medicine																						
4. Pediatrics																						
Subtotal																						
B. SPECIALTY CARE PHYSICIANS																						
1. Cardiologist																						
2. Dermatologist																						
3. Endocrinologist																						
4. Immunologist/Allergist																						
5. Infectious Disease Specialist																						
6. Gastroenterologist																						
7. General Surgeon																						
8. Nephrologist																						
9. Neurologist																						
10. Obstetrician/Gynecologist																						
11. Oncologist/Hematologist																						
12. Ophthalmologist																						
13. Orthopedist																						
14. Oral Surgeon																						
15. Otolaryngologist																						
16. Physiatrist																						
17. Psychiatrist																						
18. Pulmonologist																						
19. Urologist																						
20. Other MD/DO Only (Please Specify)																						
Subtotal																						

TABLE B: GENERAL ACUTE HOSPITALS

Note: Sort participating hospitals alphabetically by county and alphabetically within each county. If a hospital has more than one location in the county, make a separate row for each such location.

[illegible]

TABLE C: SUMMARY OF ANCILLARY, TERTIARY AND SPECIALIZED PROVIDERS BY COUNTY
(INDICATE NUMBER OF PROVIDERS IN EACH COUNTY)

Type of Provider	New Jersey Counties																						
	A T L	B E R	B U R	C A M	C A P	C U M	E S S	G L O	H U D	H U N	M E R	M I D	M O N	M O R	O C E	P A S	S A L	S O M	S U S	U N I	W A R	STATE- WIDE	
A. ANCILLARY PROVIDERS																							
1. Optometrists																							
2. Physical Therapy Centers																							
3. Psychologists																							
4.Occupational Therapy Centers																							
5. Speech Therapy Centers																							
6. Audiology Centers																							
7. Laboratory Centers																							
8. Diagnostic Radiology Centers																							
9. Home Health Agencies																							
10. MRI Centers																							
11. Other (Please Specify)																							
B. TERTIARY AND SPECIALTY																							
1. Level I and II Trauma Centers																							
2. Perinatal Service Facilities																							
3. Tertiary Pediatric Centers																							
4. Inpatient Adult Psychiatric Facilities																							
5. Outpatient Adult Psychiatric Centers																							
6. Inpatient Pediatric Psychiatric Facilities																							

TABLE C: SUMMARY OF ANCILLARY, TERTIARY AND SPECIALIZED PROVIDERS BY COUNTY
(INDICATE NUMBER OF PROVIDERS IN EACH COUNTY) *Continued*

Type of Provider	New Jersey Counties																					
	A T L	B E R	B U R	C A M	C A P	C U M	E S S	G L O	H U D	H U N	M E R	M I D	M O N	M O R	O C E	P A S	S A L	S O M	S U S	U N I	W A R	STATE- WIDE
7. Outpatient Pediatric Psychiatric Service Centers																						
8. Inpatient Rehabilitation Facilities																						
9. Outpatient Rehabilitation Centers																						
10. Inpatient Substance Abuse Facilities																						
11. Outpatient Substance Abuse Centers																						
12. Skilled Nursing Facilities																						
13. Hospice Agencies																						
14. Inpatient Radiation Therapy Centers																						
15. Outpatient Radiation Therapy Ctrs																						
16. Diagnostic Cardiac Catheterization Centers																						
Specialty Outpatient Centers:																						
HIV/AIDS Centers																						
Sickle Cell Anemia Centers																						
Hemophilia Centers																						
Craniofacial Centers																						
Congenital Anomalies Centers																						
Renal Dialysis Centers																						

Exhibit 9

Organized Delivery Systems Examples

Example 1

Nature of Services

Carrier contracts with Contractor to provide and/or arrange for the provision of certain mental health and substance abuse services to individuals covered by the Carrier's benefit plans.

Method of Payment

Carrier pays Contractor an administrative fee on a per Member Per Month basis. The Carrier is responsible for depositing amounts to pay for mental health and substance abuse services into a bank account designated by a claims administrator. The carrier is responsible for adequately funding the account, which will be used to pay claims for services received by covered persons. Providers are paid on a fee for service basis.

Determination

The Contractor is an Organized Delivery System providing limited health care services. However, the Contractor receives only an administrative fee and the Carrier is responsible for all claim costs, the Contractor does not assume financial risk. Therefore, the Contractor must apply to the Department of Health and Senior Services for Certification as an Organized Delivery System.

Example 2

Nature of Services

Carrier contracts with Contractor to provide and/or arrange for the provision of certain mental health and substance abuse services to individuals covered by the Carrier's benefit plans.

Method of Payment

Carrier pays Contractor an administrative fee on a Per Member Per Month basis subject to adjustments based on a comparison of actual claim costs to target claim costs. The Carrier is responsible for depositing amounts to pay for mental health and substance abuse services into a bank account designated by an administrator. Such funds are used to pay claims for services received by covered persons. Providers are paid on a fee for service basis.

Determination

The Contractor is an Organized Delivery System providing limited health care services. Because the Contractor shares the risk for claim costs through adjustments to the administrative fee, the Contractor does assume financial risk. Therefore, the Contractor must apply to the Department of Banking & Insurance either for licensure as an Organized Delivery System or, upon demonstration that the risk is *de minimis*,

exemption from licensure. If the Department of Banking & Insurance agrees that the risk is *de minimis*, the Contractor will be required to obtain Certification as an Organized Delivery System from the Department of Health & Senior Services.

Example 3

Nature of Services

Carrier contracts with a physician hospital organization (“PHO”) for comprehensive health care services. The PHO contracts with hospitals and physicians to provide a network for delivery of services. In some cases the PHO does not contract directly with physicians, but instead contracts with individual practice associations (“IPA”), which in turn contract with physicians other than its shareholders to provide services.

Method of Payment

Carrier pays the PHO a Per Member Per Month fee. The PHO reimburses the hospitals on a reduced fee for service basis or on a case rate basis. Generally, the physicians are paid on a capitation basis; however, specialists are reimbursed on a reduced fee for service basis. The IPAs, which are paid a Per Member Per Month fee, pay physicians on a capitation basis, and also reimburse specialists on a reduced fee for service basis.

Determination

The PHO is an Organized Delivery System providing comprehensive health care services and assuming financial risk. Therefore, the PHO must apply to the Department of Banking and Insurance either for licensure as an Organized Delivery System or, upon demonstration that the risk is *de minimis*, exemption from licensure. The IPAs, which indirectly provide a network of providers to the carrier, are also risk assuming and must apply either for licensure as Organized Delivery Systems or, upon demonstration that the risk is *de minimis*, exemption from licensure. If an exemption is granted by the Department of Banking and Insurance, then certification from the Department of Health and Senior Services must be sought.